National Breast and Cervical Cancer Early Detection Program

Policies and Procedures Manual

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
Division of Cancer Prevention and Control

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A. Overview of Manual

1. Purpose

This Policies and Procedures Manual provides descriptions and explanations of the law, as well as National Breast and Cervical Cancer Early Detection Program (NBCCEDP) cooperative agreement and program management policies and procedures. This Manual does not replace the NBCCEDP Orientation Manual (March 1997), but supplements it. The information in this Manual supercedes similar information contained in the Orientation Manual. It is recommended that you remove the "Management" section of the Orientation Manual and, instead, refer to this Manual for management guidance.

The intended audience for this Manual includes all staff of NBCCEDP programs. As with any project, this Manual is a work in progress. As new policies and supporting materials are developed, they will be forwarded to you for insertion into this binder.

2. Content

This first section of the Manual, "Introduction," describes the role of the Division of Cancer Prevention and Control, pertinent legislation and reauthorization language.

The second section of the Manual, "Cooperative Agreement Management," addresses cooperative agreement management requirements, policies, and funding approaches.

The third section of the Manual, "Program Management," describes three tools that have been developed to assess the infrastructure development and service delivery aspects of the NBCCEDP, including the Minimum Data Elements (MDE's), the System for Technical Assistance Reporting (STAR), and the Program Progress Review. This information spans across and connects all program components, including:

- Management;
- Coalitions and Partnerships;
- Public Education and Outreach;
- Quality Assurance and Improvement;
- Professional Education;
- Screening, Tracking, Follow-up, and Case Management; and,
- Surveillance and Evaluation.

Figure 1 depicts the relationship among these various interdependent components.

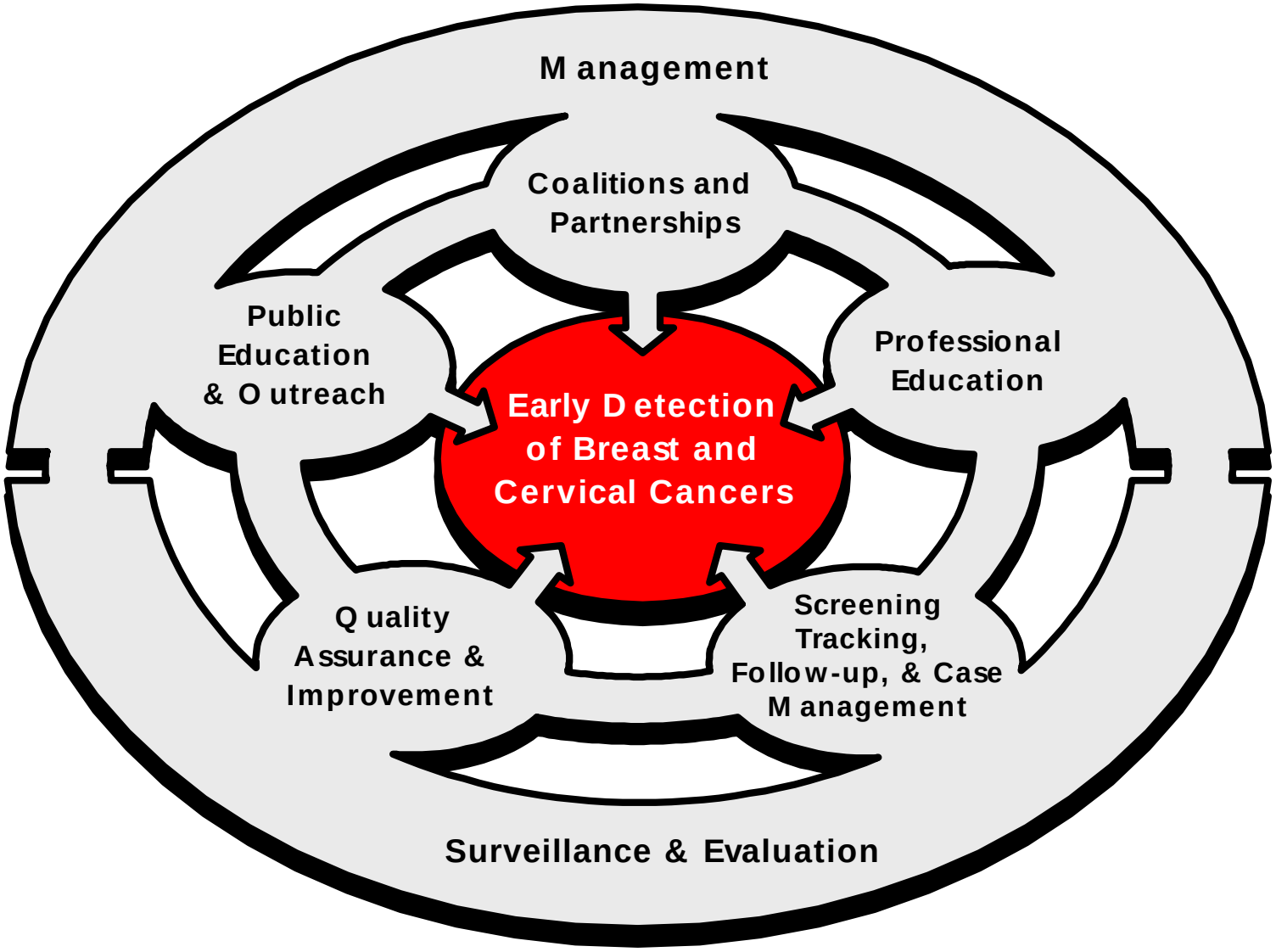
The fourth section of the Manual, "Program Policies," contains the official policies for NBCCEDP. These policies mandate specific requirements in relation to:

- Reimbursement for Screening and Diagnostic Services;
- Inclusion of Data in the Minimum Data Elements;
- Timeliness and Adequacy of Follow-up;
- Rescreening;
- Case Management.

The fifth section of the Manual, "References," provides additional resources to support the policies and procedures described in this Manual.

Figure I-1

The Relationship of National Breast and Cervical Cancer Early Detection Program Components



CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

B. Cancer Prevention and Control at CDC

1. Division Mission

A recognized leader in cancer control and prevention, the Division of Cancer Prevention and Control (DCPC), which is part of CDC's NCCDPHP, implements programs for the nation. The Division is a leader for nationwide cancer prevention and control, a partner with State, tribal and territorial health departments and other key groups, and a link between science and intervention, through surveillance and applied research.

CDC's national program to reduce the burden of cancer in the United States has the following mission:

- To plan, direct, and support cancer control efforts through collaborations with prevention partners in State, tribal and territorial health agencies, Federal agencies, academic institutions, and national, voluntary, and private sector organizations.

- To direct, monitor, and report on activities associated with the implementation of the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) and the Cancer Registries Amendment Act (Public Law 102-515).

- To plan and conduct epidemiological studies and evaluations to identify the feasibility and effectiveness of cancer prevention and control strategies. DCPC provides State, tribal and territorial public health agencies and other health care provider organizations with technical consultation and assistance to improve education, training, and skills in the prevention, detection, and control of selected cancers, including colorectal, prostate, and skin cancers.

- To identify problems, needs, and opportunities related to modifiable behavioral and other risk factors. The Division also recommends priorities for health promotion, health education, and cancer risk reduction activities both for professionals and the public. DCPC pursues the building of local coalitions and community networks and the implementation of grassroots activities to reach the target populations of persons at increased risk for developing cancer.

2. Division Organizational Structure

DCPC has six major activities, which are reflected in its organizational structure (See page I-8 for the Division Organizational Chart).

Program Support Activity
The Program Support Activity (PSA) manages the Division's administrative and fiscal responsibilities. Budgetary and personnel issues are coordinated for the Division through this office. The Program Support Activity is the administrative liaison for the Division to the NCCDPHP.

Office of Program and Policy Information
The Office of Program and Policy Information (OPPI) is responsible for strategic development, legislative monitoring and analysis, and implementation and coordination of external affairs to promote CDC's DCPC mission and programs. OPPI also promotes collaboration with public- and private-sector organizations designed to advance the DCPC mission. It manages DCPC information services, including internal and external communications, congressional briefing reports, and media inquiries. OPPI also coordinates the production of DCPC information tools, such as At-A-Glances, that are disseminated to broad audiences.

To further these objectives, OPPI maintains a library of publications, speeches, slides, and other media produced to advance the mission of DCPC programs. OPPI is the liaison to the public, health professionals, and the media. OPPI maintains a home page on the Internet and, by invitation, sends exhibits to various conferences, meetings, and events sponsored by DCPC programs and partners.

Communication and Behavioral Sciences Branch
In 1997, DCPC established the Communication and Behavioral Sciences Branch (CBSB), to lead the strategic planning, formative research, implementation, and evaluation of health communication campaigns that will target skin, breast, cervical, colorectal, and prostate cancers. Consistent with CDC's definition of health communication, CBSB will use research methods and findings from the behavioral and social sciences, health education, mass communication, and social marketing to craft and deliver messages and strategies to improve the health of individuals and communities. In addition, this Branch will have the lead responsibilities for communication and media analysis, and behavioral science research and evaluation. In addition, the CBSB will promote collaboration with public- and private- sector organizations designed to advance the Division's mission and programs.

Epidemiology and Health Services Research Branch

The Epidemiology and Health Services Research Branch (EHSRB), formerly the Epidemiology and Statistics Branch, was formed through a Division reorganization in 1997. The Branch consists of clinicians and epidemiologists who conduct data analysis and research projects on major cancer issues. In addition, EHSRB provides the Division with clinical and scientific interpretation of data collected in the NBCCEDP. EHSRB works with the Program Services Branch (PSB) and a contractor, Information Management Services (IMS), to monitor and analyze all data collected from programs participating in NBCCEDP. EHSRB works collaboratively with PSB to review and analyze data routinely to address clinical and data issues and provide assistance to programs participating in NBCCEDP as needed. Significant health findings are often published in scientific journals.

Cancer Surveillance Branch

The Cancer Surveillance Branch (CSB), formed in 1997 as a part of a Division reorganization, provides leadership, technical assistance, and support to programs for the planning, implementation, and evaluation of population-based, statewide central cancer registries which serve as the foundation for comprehensive, integrated cancer control programs. In addition, Branch staff collaborate with other Federal, State, territorial, tribal, private, and international organizations to improve national and worldwide cancer surveillance; improve accessibility and utilization of population-based cancer surveillance data; and, develop and disseminate standards for cancer data completeness, timeliness, and quality. The Branch also contributes to the enhancement, design, and analysis of information systems for the surveillance, collection, and analysis of cancer data; plans, designs, and conducts research using cancer surveillance data; and, helps monitor trends in cancer risk factors, incidence, mortality, and survival for cancer prevention and control.

Program Services Branch

The Program Services Branch (PSB) provides national leadership, guidance, and support for the development, implementation, and evaluation of cancer prevention and control programs. The Branch staff is a multi-disciplinary team consisting of public health professionals with training in health education, nursing, medicine, public administration, health policy and administration, and social work(See page I-9 for the PSB Organizational Chart). PSB staff have the lead responsibility for providing technical assistance and consultation to state and territorial health agencies, tribes and tribal organizations, and national organizations. The Branch manages the NBCCEDP, the Breast and Cervical Cancer Replication and Dissemination Program, Comprehensive Cancer Control Program, and Skin Cancer Prevention Education and Colorectal Cancer Control programmatic activities.

The PSB overall goals include:

- Foster the development and implementation of cancer prevention and control programs and services.

- Promote programmatic evaluation and translate research into recommendations for action.

- Strengthen relationships with our existing partners and build new coalitions and alliances with private and public sector organizations.

- Provide education, training, and technical support opportunities for our partners and staff to facilitate the development of knowledge, skills, and abilities needed to accomplish the mission.

Figure 2: Division Organizational Chart

Division of Cancer Prevention and Control
National Center for Chronic Disease Prevention and Health Promotion

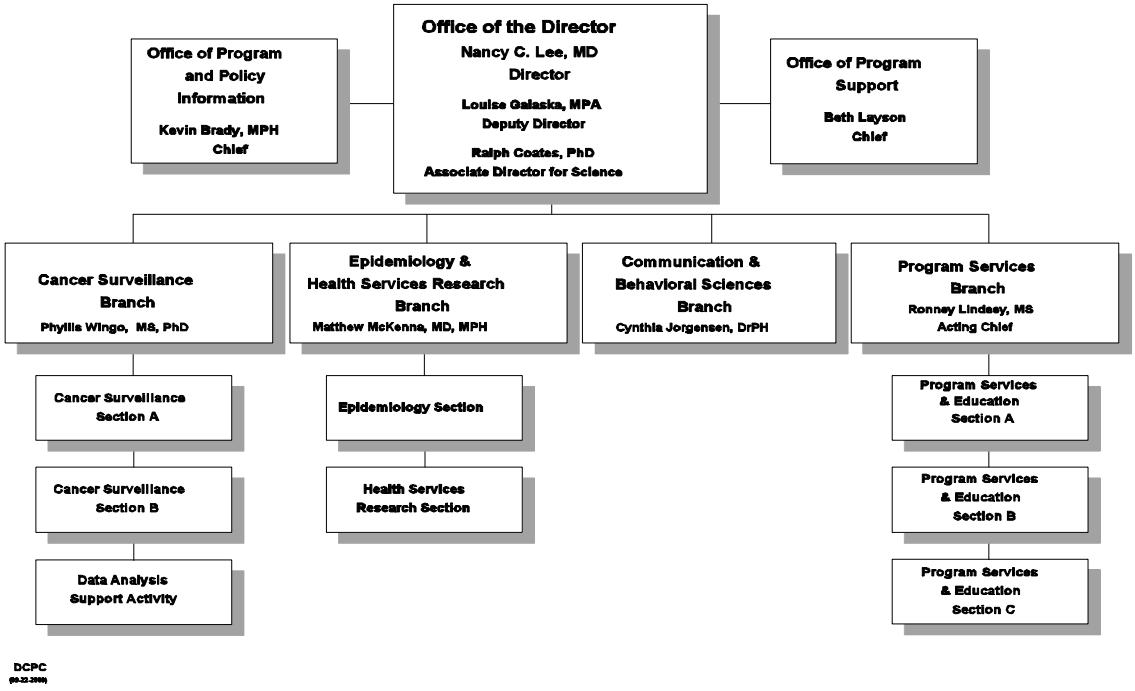
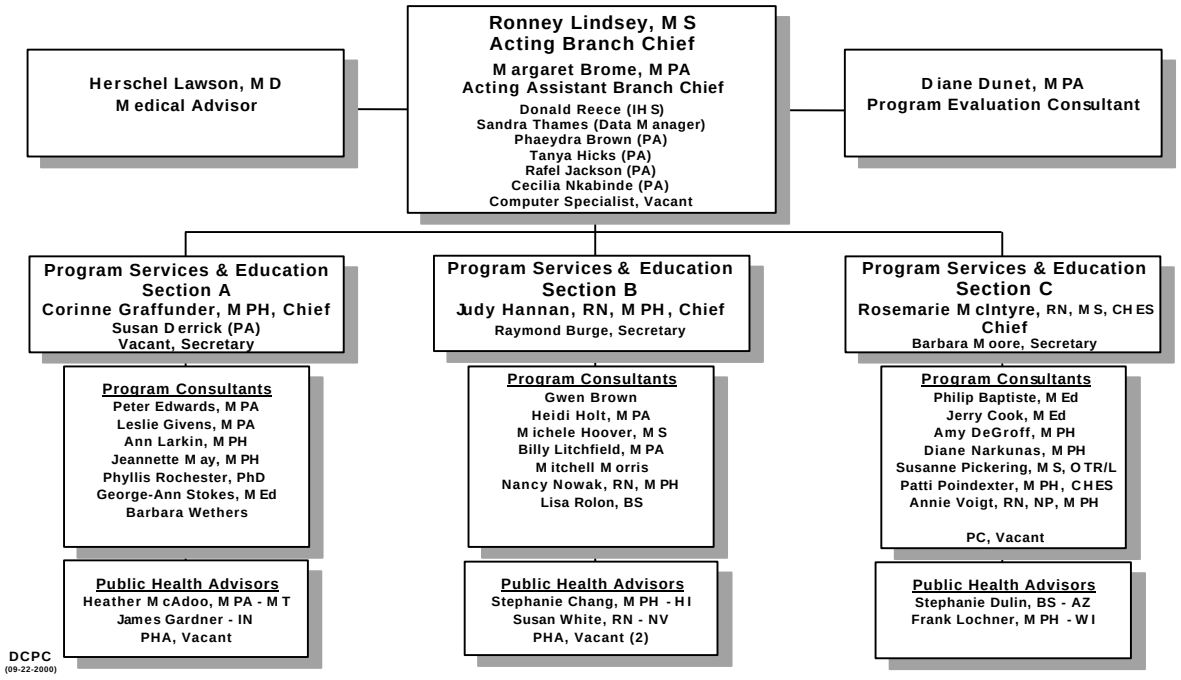


Figure 3: PSB Organizational Chart

Program Services Branch
Division of Cancer Prevention and Control
National Center for Chronic Disease Prevention and Health Promotion



3. Program Consultants' Responsibilities Related to the NBCCEDP

CDC Program Consultants are liaisons between the PSB and NBCCEDP cooperative agreement recipients, which include State and territorial health organizations and tribes and tribal organizations. Their primary role is to provide technical assistance and consultation to NBCCEDP-sponsored programs in all programmatic component areas. In addition, program consultants monitor and manage cooperative agreements to assist programs in complying with legal and administrative cooperative agreement requirements. The position requires an understanding of cancer prevention and control, the expertise to anticipate potential programmatic or administrative challenges, and the ability to recognize when appropriate and timely involvement of others, such as PSB management staff or professional experts, may be necessary to resolve complex programmatic and administrative issues. A detailed list of responsibilities follows.

Technical Assistance and Consultation

- Provide consultation and technical assistance to grantees, via site visits and conference calls, to plan, implement and manage all programmatic components of NBCCEDP. These components include screening, tracking, follow-up, case management, public education, professional education, quality assurance and improvement, coalition/partnership development, surveillance and evaluation.

- Identify innovative programmatic or administrative strategies to address complex technical assistance needs.

- Provide clear explanations of CDC policies and procedures, current program activities, and future directions.

- Serve as a resource to alternative sources of information in other programs at or funded by CDC, Federal agencies, and/or national and professional organizations.

- Review MDE submissions and STAR reports (see Section III - Program Management) and develop appropriate follow-up action plans.

Cooperative Agreement Management

- Assist grantees to identify and provide all required information in order to remove programmatic or budgetary restrictions.

- Assist grantees to ensure that program expenditures are in accordance with Public Law 101-354 and its amendments, regulations, and programmatic and budgetary policies.

- Facilitate communication with the Procurement and Grants Office (PGO) for timely response to grantee requests for budgetary actions.

4. Field Staff

DCPC provides on-site assistance to State health agencies through the assignment of field staff. The Division has 10 field staff assigned to state health agencies to assist with the implementation of state breast and cervical cancer early detection programs. In addition, these staff serve as a CDC liaison in the assigned state health departments. These staff have diverse backgrounds and offer a broad range of professional experience in public health.

C. Pertinent Legislation

The following chapter of the US Code incorporates Public Law (PL) 101-354, which established NBCCEDP, and it's amendments, PL 103-183, which amended the legislation to include American Indian/Alaska Native tribes and tribal organizations, and PL 105-340, the Women's Health Research and Prevention Amendments of 1998, signed 10/31/98, which added case management as a program component and changed the programs' ability to contract with for-profit entities.[1]

Title 42. The Public Health and Welfare
Chapter 6a. The Public Health Service
Preventive Health Measures with Respect to Breast and Cervical Cancers
42 U.S.C. § 300k (1998)

§ 300k. Establishment of program of grants to States

(a) In general. The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States on the basis of an established competitive review process for the purpose of carrying out programs--

(1) to screen women for breast and cervical cancers as a preventive health measure;

(2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services ***and support services such as case management***;

(3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancers;

(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancers;

(5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancers, including the interpretation of such procedures; and

(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.

(b) Grant and contract authority of States.

(1) In general. A State receiving a grant under subsection (a) may, subject to paragraphs (2) and (3), expend the grant to carry out the purpose described in such

[1]Italicized text shows changes made by the Women's Health Research and Prevention Amendments of 1998, Public Law 105-340, signed October 31, 1998.

subsection ***through grants to public and non-profit private entities and through contracts with public and private entities.***
(2)CERTAIN APPLICATIONS—If a nonprofit private entity and a private entity that is not a nonprofit entity both submit applications to a State to receive an award of a grant or contract pursuant to paragraph (1), the State may give priority to the application submitted by the nonprofit private entity in any case in which the State determines that the quality of such application is equivalent to the quality of the application submitted by the other private entity.
(3) Payments for screenings. The amount paid by a State to an entity under this subsection for a screening procedure under subsection (a)(1) may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act [42 U.S.C. §§ 1395j et seq.] if payment were made under such part for furnishing the procedure to a woman enrolled under such part.

(c) Special consideration for certain States. In making grants under subsection (a) to States whose initial grants under such subsection are made for fiscal year 1995 or any subsequent fiscal year, the Secretary shall give special consideration to any State whose proposal for carrying out programs under such subsection—

(1) has been approved through a process of peer review; and
(2) is made with respect to geographic areas in which there is—
(A) a substantial rate of mortality from breast or cervical cancer; or
(B) a substantial incidence of either of such cancers.

[(d)](c) Coordinating committee regarding year 2000 health objectives. The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to coordinate the activities of the agencies of the Public Health Service (and other appropriate Federal agencies) that are carried out toward achieving the objectives established by the Secretary for reductions in the rate of mortality from breast and cervical cancer in the United States by the year 2000. Such committee shall be comprised of Federal officers or employees designated by the heads of the agencies involved to serve on the committee as representatives of the agencies, and such representatives from other public or private entities as the Secretary determines to be appropriate.

§ 300l. Requirement of matching funds

(a) In general. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(b) Determination of amount of non-Federal contribution.

(1) In general. Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.
(2) Maintenance of effort. In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose described in section 1501 [42 U.S.C. § 300k] for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.
(3) Inclusion of relevant non-Federal contributions for Medicaid. In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to Title XIX of the Social Security Act [42 U.S.C. § 1396 et seq.] by the State involved toward the purpose described in paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)].

§ 300l-1. Requirement regarding medicaid

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] for a program in a State unless the State plan under title XIX of the Social Security Act [42 U.S.C. §§ 1396 et seq.] for the State includes the screening procedures specified in subparagraphs (A) and (B) of section 1503(a)(2) [42 U.S.C. § 300m(a)(2)(A), (B)] as medical assistance provided under the plan.

§ 300m. Requirements with respect to type and quality of services

(a) Requirement of provision of all services by date certain. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees—
(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)], including making available screening procedures for both breast and cervical cancers;
(2) subject to subsection (b), to ensure that—
(A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and
(B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a Pap smear are conducted;
3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 1501(a) [42 U.S.C. § 300k(a)] is provided; and
(4) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.

(b) Use of improved screening procedures. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use, any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.

(c) Quality assurance regarding screening procedures. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the State will, in accordance with applicable law, assure the quality of screening procedures conducted pursuant to such section.

§ 300n. Additional required agreements

(a) Priority for low-income women. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)].

(b) Limitation on imposition of fees for services. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981 [42 U.S.C. § 9902(2)].

(c) Statewide provision of services.

(1) In general. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that services and activities under the grant will be made available throughout the State, including availability to members of any Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act [25 U.S.C. § 450b]).

(2) Waiver. The Secretary may waive the requirement established in paragraph (1) for a State if the Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 1501(a) [42 U.S.C. § 300k(a)].

(3) Grants to tribes and tribal organizations.

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to tribes and tribal organizations (as such terms are used in paragraph (1)) for the purpose of carrying out programs described in section 1501(a) [42 U.S.C. § 300k(a)]. This title

applies to such a grant (in relation to the jurisdiction of the tribe or organization) to the same extent and in the same manner as such title applies to a grant to a State under section 1501 [42 U.S.C. § 300k] (in relation to the jurisdiction of the State).

(B) If a tribe or tribal organization is receiving a grant under subparagraph (A) and the State in which the tribe or organization is located is receiving a grant under section 1501 [42 U.S.C. § 300k], the requirement established in paragraph (1) for the State regarding the tribe or organization is deemed to have been waived under paragraph (2).

(d) Relationship to items and services under other programs. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) Coordination with other breast and cervical cancer programs. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the services and activities funded through the grant shall be coordinated with other Federal, State, and local breast and cervical cancer programs.

(f) Limitation on administrative expenses. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(g) Restrictions on use of grant. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(h) Records and audits. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that—

(1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section; and

(2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.

(I) Reports to Secretary. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

§ 300n-1. Description of intended uses of grant

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 1501(a) [42 U.S.C. § 300k(a)];

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public and nonprofit private entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

§ 300n-2. Requirement of submission of application

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in section 1505 [42 U.S.C. § 300n-1], and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this title [42 U.S.C. §§ 300k et seq.].

§ 300n-3. Technical assistance and provision of supplies and services in lieu of grant funds

(a) Technical assistance. The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 1501 [42 U.S.C. § 300k]. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(b) Provision of supplies and services in lieu of grant funds.

(1) In general. Upon the request of a State receiving a grant under section 1501 [42 U.S.C. § 300k], the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in payments. With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 1501 [42 U.S.C. § 300k] to the State involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

§ 300n-4. Evaluations and reports

(a) Evaluations. The Secretary shall, directly or through contracts with public private entities, provide for annual evaluations of programs carried out pursuant to section 1501 [42 U.S.C. § 300k]. Such evaluations shall include evaluations of the extent to which States carrying out such programs are in compliance with section 1501(a)(2) [42 U.S.C. § 300k(a)(2)] and with section 1504(c) [42 U.S.C. § 300n(c)].

(b) Report to Congress. The Secretary shall, not later than 1 year after the date on which amounts are first appropriated pursuant to section 1509(a) [42 U.S.C. § 300n-5(a)], and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this title [42 U.S.C. §§ 300k et seq.] as the Secretary determines to be appropriate, including recommendations regarding compliance by the States with section 1501(a)(2) [42 U.S.C. § 300k(a)(2)] and with section 1504(c) [42 U.S.C. § 300n(c)].

§ 300n-4a. Supplemental grants for additional preventive health services

(a) Demonstration projects. In the case of States receiving grants under section 1501 [42 U.S.C. § 300k], the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to not more than 3 such States to carry out demonstration projects for the purpose of—

(1) providing preventive health services in addition to the services authorized in such section, including screenings regarding blood pressure and cholesterol, and including health education;

(2) providing appropriate referrals for medical treatment of women receiving services pursuant to paragraph (1) and ensuring, to the extent practicable, the provision of appropriate follow-up services; and

(3) evaluating activities conducted under paragraphs (1) and (2) through appropriate surveillance or program-monitoring activities.

(b) Status as participant in program regarding breast and cervical cancers. The Secretary may not make a grant under subsection (a) unless the State involved agrees that services under the grant will be provided only through entities that are screening women for breast or cervical cancer pursuant to a grant under section 1501 [42 U.S.C. § 300k].

(c) Applicability of provisions of general program. This title [42 U.S.C. §§ 300k et seq.] applies to a grant under subsection (a) to the same extent and in the same manner as such title applies to a grant under section 1501[42 U.S.C. § 300k].

(d) Funding.

(1) In general. Subject to paragraph (2), for the purpose of carrying out this section, there are authorized to be appropriated $ 3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 ***through 2003***.

(2) Limitation regarding funding with respect to breast and cervical cancers. The authorization of appropriations established in paragraph (1) is not effective for a fiscal year unless the amount appropriated under section 1510(a) [42 U.S.C. § 300n-5(a)] for the fiscal year is equal to or greater than $ 100,000,000.

§ 300n-5. Funding for general program

(a) Authorization of appropriations. For the purpose of carrying out this title [42 U.S.C. §§ 300k et seq.], there are authorized to be appropriated $ 50,000,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, $ 150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 ***through 2003***.

(b) Set-aside for technical assistance and provision of supplies and services. Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507 [42 U.S.C. § 300n-3].

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National Breast and Cervical Cancer Early Detection Program Cooperative Agreement Management Requirements

April 1, 1994
(revised February 1999)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
Division of Cancer Prevention and Control

Introduction

The scope of fiscal responsibility in the NBCCEDP is enormous given the amount of funds awarded to programs and the implementation challenges related to the administrative requirements of the "Breast and Cervical Cancer Mortality Prevention Act of 1990" (Public Law 101-354) and its amendments, the "Breast and Cervical Cancer Amendments of 1993" (Public Law 103-183) and the "Women's Health Research and Prevention Amendment of 1998" (Public Law 105-340). Sound fiscal management with a close and coordinated working relationship among program and fiscal managers, program staff, service providers, and other contractors is essential. CDC is committed to providing clear guidance to programs for the management of cooperative agreement funds. Most importantly, CDC is committed to implementing programs using a management philosophy that values input from program managers and recognizes these partnerships as essential.

CDC anticipates that the guidance contained in the following pages will evolve with program growth and amendments to the authorizing legislation. This guidance, however, is not meant to supercede the Public Health Service (PHS) Grants Policy Statement (see references section), but rather aims to explain its concepts in terms relevant to the NBCCEDP. This information will be updated on a regular basis.

Please direct all requests for programmatic technical assistance to *your* program consultant at:

Program Services Branch
Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention
and Health Promotion
Division of Cancer Prevention and Control
Mailing Address:
4770 Buford Highway, N.E., MS K-57
Atlanta, GA 30341-3724
Telephone (770) 488-4880
Fax (770) 488-4727
Federal Express Address:
2858 Woodcock Boulevard
Room (insert room number here)
Atlanta, GA 30341
(770) 488-4880

Please direct all official fiscal communication (be sure to discuss with your program consultant first), including continuation applications, and requests for prior approval, to the Procurement and Grants Office (PGO) at:

Mildred Garner
Grants Management Officer
Grants Management Branch
Procurement and Grants Office
Mailstop E-18
2920 Brandywine Drive
Atlanta, GA 30341

DCPC has worked closely with CDC's legal counsel and PGO in addressing NBCCEDP cooperative agreement management requirements and guidelines. The following pages present the intent of the U.S. Congress as expressed in the "Breast and Cervical Cancer Mortality Prevention Act of 1990" (Public Law 101–354), the "Breast and Cervical Cancer Amendments of 1993" (Public Law 103–183), the "Women's Health Research and Prevention Amendments" of 1998, (Public Law 105-340) and supported by PHS Grants Policy Statement.

A. Criteria for Funding Cooperative Agreements

In addition to the criteria outlined in the PHS Grants Policy Statement (see "References," Section V), several items are considered in determining funding levels for new and continuation awards.

1. New Awards

- Approval for funding per objective review process;
- Availability of funds;
- Sufficiently high application score; and,
- Appropriateness of requested budget line items.

2. Continuation Awards or Previously Funded Programs Receiving New Awards

- Adequacy of proposed program plans for next year;
- Appropriateness of requested budget line items;
- Availability of funds;
- Amount of unobligated program funds; and,
- Program performance during previous project periods, relative to performance indicators.

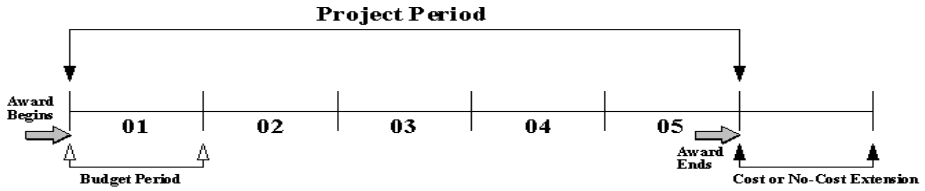
B. Cooperative Agreement Management Principles and Terminology

Once funding has been awarded, NBCCEDP funded programs become responsible for the appropriate distribution and use of these funds. The following definitions and explanations of time periods and budget concepts must be considered when allocating program funds for the NBCCEDP.

Additional information may be obtained in the PHS Grants Policy Statement and the DHHS GrantsNet internet site (See "References," Section V).

Figure II-1.

Interrelationship of Project Period, Budget Period, Cost and No-Cost Extension



1. Interrelated Time Periods

Throughout the duration of this cooperative agreement, certain interrelated time periods may exist, including a project period, budget periods, and cost and no-cost extensions (see Figure II-1). These time periods are defined as follows.

2. Project Period

Cooperative agreements for the NBCCEDP are awarded for a 5 year project period.

3. Budget Period

During the project period, program budgets are awarded annually for 12-month budget periods, amounts awarded are subject to the availability of new CDC funds each year and the amount of unobligated funds remaining at the program level.

4. No-Cost Extension

An extension of time to a project period and/or budget period to complete previously approved activities. The no-cost extension is subject to an approved work-plan and budget. No additional funds are awarded or competition is required with a no-cost extension.

5. Cost Extension

An extension of time to a project period and/or budget period to complete previously approved activities. The cost extension is subject to an approved work-plan and budget. A minimal amount of Federal funds would be awarded but no competition is required with a cost extension.

6. Total Budget Concept

The money awarded to programs through cooperative agreements in the NBCCEDP is based on a total budget concept, which includes financial assistance (FA), direct assistance (DA), and matching funds. The Notice of Cooperative Agreement Award (NCA) generated by CDC reflects this total budget.

7. Financial Assistance (FA)

Financial assistance refers to Federal money awarded in cash to support program activities authorized in Public Law 101–354. The amount of financial assistance is negotiated by object class category (Standard Form 424A) with funded programs and is based on the proposed budget and justification and the criteria for new and continuation cooperative agreements. Official notification of financial assistance is provided to funded programs in the NCA issued by the CDC PGO and may be composed of new funds, supplemental funds, and/or unobligated or carry over funds. Each cooperative agreement will receive funds that will be identified as the "base award" — the amount CDC commits to the recipient if funds allow.

8. Direct Assistance (DA)

Direct assistance refers to Federal money awarded in lieu of cash to assign a Federal employee in a funded program as authorized in Public Law 101–354. The amount of direct assistance supports salary, fringe, travel, and other costs associated with the assigned Federal employee. Official notification of direct assistance is provided to funded programs in the Notice of Cooperative Agreement Award (NCA) issued by the CDC PGO.

9. Contract Periods of Performance

A contract period of performance is the duration of a contract. Service delivery contracts are initiated with providers who conduct the screening and diagnostic tests and the referral and follow-up activities. Because the program is the payor of last resort, it may take 3 or 4 months before a contracted provider bills the program for services rendered. Such delays in billing present a major challenge to programs in managing program funds.

At the same time, it is important for a funded program to monitor and manage its unobligated FA funds. The deadline date for liquidating obligations of the previous

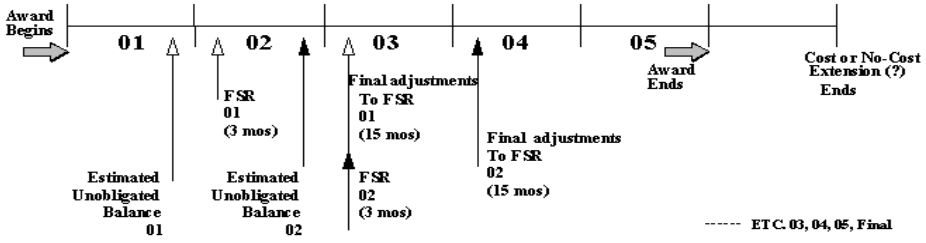
budget year is 90 days after the end of a budget year. A deadline for liquidating obligations of the previous budget year is necessary to allow effective management of program funds, encourage fiscal responsibility, and provide adequate time for contract approvals at CDC. After the deadline, the remaining FA funds become unobligated, are reported on the Financial Status Report (FSR) (see below) for that year, and become available to the NBCCEDP-funded program on written request.

10. Financial Status Reports (FSR)

A FSR is the mechanism by which unobligated FA funds are officially reported to CDC (Please see References section for a sample FSR). An FSR is required for each budget period and the final project period (see Figure II-2). Ninety days after the end of each budget period, an FSR is due to the CDC Grants Management Office. However, adjustments may be made up to 15 months after the end of the **budget period**. Programs can submit documentation of their current year's estimated unobligated dollars on their 424-A or via letter prior to the end of the project or approved no-cost or cost extension period (see Figure II-2).

Figure II-2.

Monitoring Unobligated Funds
Financial Status Reports (FSR)



It is important that unobligated funds be accurately monitored and reported in the FSRs. The close monitoring of unobligated FA funds is vitally important in the programs because of the large amount of program dollars awarded. Programs should have a clear understanding of the amount of unobligated funds available before requesting approval to use unobligated FA funds in the program.

If inaccurate financial accounting occurs, which may be reflected on the FSR submitted to CDC, there are two potential outcomes—an overestimation or underestimation of unobligated FA funds. *Overestimation* of the actual unobligated balance may result in a reduction of the current year's total budget award. *Underestimation* of the actual unobligated balance may result in the reduction of new funds available for future budget periods.

For example, a problem can occur when a program overestimates the amount of unobligated FA dollars in an FSR and receives subsequent approval from CDC to utilize these funds, or CDC chooses to use the unobligated funds to make up the program's base award in the subsequent budget year. If it is determined that there were actually fewer unobligated FA dollars, the program's current budget award may be reduced accordingly by CDC for the amount overestimated. A program is informed of this potential outcome and it is reflected in its revised Notice of Cooperative Agreement Award.

A serious situation can occur when unobligated funds are overestimated and this problem is not identified until the end of the project or approved no-cost extension period. Essentially, this means that more cooperative agreement funds were spent than awarded and the program would have to repay the Federal Government the amount overspent.

On the other hand, inaccurate financial accounting could result in the return of unspent funds to the U.S. Treasury at the end of the project or approved no-cost extension period. These funds can no longer be used in the program!

11. Management of Unobligated Financial Assistance Funds

DCPC and PGO will provide consultation to individual programs for the effective use of their unobligated funds and for the management of future program expenditures. Unobligated funds may arise from FA and DA. In the NBCCEDP, FA and DA amounts will always be managed separately. Unobligated FA funds are one-time only funds, and are to be used for non-recurring activities. Once awarded, unobligated funds must be spent by the end of that budget year or they once again become unobligated funds. The close monitoring of unobligated FA funds is vitally important in the programs because of the large amount of program dollars awarded. Programs should have a clear understanding of the amount of unobligated funds available before requeting approval to use unobligated FA funds in the program. When submitting a continuation application, programs must submit an estimated FSR for the current budget period. See Pages II-6&7 for further details on submitting FSR's. If an estimated FSR is submitted for a budget year, and a final accounting is unavailable, only 75% of those estimated unobligated FA funds may be requested.

The PHS Grants Policy Statement states that "The PHS awarding office exercises sole discretion as to the use of unobligated grant funds." (see Section V- References, page 5-2) In accordance with all laws and regulations, carryover of unobligated balances by the grantee is authorized only from one budget period to the next.

12. Management of Unobligated Direct Assistance Funds

The DA amount is budgeted to support the cost of a CDC public health advisor. Not all programs have DA. For those programs that have a public health advisor, CDC will manage unobligated DA funds and will inform programs on the status of these expenditures annually after the end of the budget period. At the discretion of CDC, unobligated DA funds may be converted to unobligated FA at the program or CDC's request. Unused unobligated DA may revert to the treasury if not spent or converted to FA and spent.

13. Prior Approvals

CDC requires that certain program changes receive prior approval from PGO. Failure to obtain prior approval, when required, may result in disallowance of costs. Examples of these changes include: a change in principal investigator, spending restricted funds, subcontracting supervision of a substantial amount of work, spending unobligated funds, cost or no-cost extensions, and certain expenditures for advisory boards. A complete list and additional guidance are available in the PHS Grants Policy Statement, Section 8-4, found in the Reference section of this Manual.

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C. Cooperative Agreement Management Legislative Requirements

Public Laws 101–354, 103–183, and 105-340, authorize States/tribes/territories to spend Federal monies for:

- Screening women;
- Tracking and ensuring follow-up;
- Case management;*
- Developing and disseminating public information and education programs;
- Improving the education, training, and skills of health professionals;
- Monitoring the quality and interpretation of screening procedures;
- Designing and monitoring surveillance systems; and,
- Evaluating activities.

A description of the types of services and activities that are included in the functional cost centers for each of these program components follows on pages II-11 through II-16.

*Reauthorization language for FY 1999 included case management as an authorized expense for the NBCCEDP.

There are several unique budgetary requirements for the NBCCEDP outlined in Public Law 101-354 and its amendments with which programs must comply:

1. 60 Percent/40 Percent Distribution Requirement

The following guidance is intended to clarify and define costs that are allowable in the 60 percent and 40 percent distribution categories. These distribution categories use the related functional cost center as a classification system to define and to allocate program costs.

60 Percent Distribution. Costs allowable in the 60 percent category are allocated in the following functional cost center:

- Screening, Tracking, Follow-up and Support Services;

40 Percent Distribution. Costs allowable in the 40 percent category are allocated in the following functional costs centers.

- Management
- Public education and Outreach
- Professional Education
- Quality Assurance and Improvement
- Coalitions and Partnerships
- Surveillance and Evaluation

The basis for calculating the 60/40 percent distribution is based on the total amount of Federal monies (financial assistance and direct assistance) awarded to the program . It does not apply to the non-Federal matching funds.

Calculation of 60/40 Distribution Requirement

	Example
FA	2.9 M
DA	.1 M
Total	3.0 M
3.0 M x 60 percent	= 1.8 M
3.0 M x 40 percent	= 1.2 M

The Cost Center model is used to assure the development and implementation of a program that is in compliance with the Public Law, Early Detection Guidelines, and policies governing the NBCCEDP.

A. Screening, Tracking, Follow-up and Support Services Functional Cost Center

All costs incurred in providing screening services, including the tracking and follow-up for *individually* screened women with abnormal screening results. These services are defined by the following subcategories:

Screening, Tracking and Follow-upServices — Costs of screening and appropriate diagnostic procedures incurred for breast and cervical cancer. In the case of breast cancer, screening procedures include both a physical examination of the breast and mammography. With cervical cancer, screening procedures include pelvic examination and Pap smear. Payment for screening procedures includes reimbursement of health care provider time or fees for office visits and clinical evaluation, and related co-pays and deductibles for eligible women. This may include clinical supplies and equipment directly related to the provision of screening and diagnostic services. This cost center

also includes the costs incurred to establish and maintain a proactive tracking and recall system for the purposes of directly contacting women for follow-up services and ensuring the initiating of any treatment if needed, and the cost of client records associated with the diagnostic procedures. (For further guidance, including appropriate diagnostic procedures, see Program Policies section "Reimbursement Policies for Screening and Diagnostic Services.")

Laboratory— Cost of laboratory services, performed either onsite or offsite, for evaluation of Pap smears and evaluation of tissue specimens from diagnostic procedures.

Essential Screening Support Services— This subcategory includes costs for ancillary screening, tracking, follow-up and case management services including:

- *Client Intake*. Costs incurred for individual client eligibility determination, such as age and financial status, whether such means-testing results in screening or not.
- *Client Tracking.* Costs incurred in assisting individual clients with abnormal findings to obtain diagnostic and treatment services if necessary. This category includes outreach via home visits to resolve missed appointments and assistance in obtaining diagnostic and treatment services from medical and social service agencies.
- *Client Counseling.* Costs incurred for individual client counseling relating to screening, diagnostic and treatment services.
- *Client Case Management.* Costs incurred for individual client assessment, planning coordination, monitoring, and resource development as defined by NBCCEDP's Case Management Policy effective September 30, 1999 are allowable under this cost center. (Please note, not all activities included within a program's case management operational plan are allowable under this cost center, only those pertaining to the case management of an individual client.)
- *Client Transportation.* Costs incurred in providing transportation to assist individual clients in keeping their appointments at screening and diagnostic provider sites.
- *Client Translation*. Costs incurred in providing translation services to assist individual clients in communicating with providers.
- *1:1 Outreach.* Costs incurred in conducting activities specifically designed to provide outreach, recruitment and enrollment to an individual woman. Examples of these activities include door to door outreach and recruitment, and direct phone contact for recruitment and enrollment purposes.

B. Management Functional Cost Center

Costs in this cost center are allocated to assure infrastructure development to optimize the use of program resources. Costs include the development and integration of a strategic plan, based on goals and measurable objectives, that is responsive to the characteristics and needs of the priority populations. Other costs include the recruitment and development of a technically diverse and skilled staff; the establishment and maintenance of fiscal tracking and reimbursement systems; the establishment and monitoring of contracts with providers for the delivery of screening and follow-up services; the use of surveillance/evaluation data for program monitoring and decision making; and any other related management and administrative costs.

C. Public Information, Education and Outreach Functional Cost Center

Costs incurred to develop and disseminate public information and education programs for the early detection and control of breast and cervical cancer fall into this functional cost center. Programs should distinguish between costs for group information (public information, education and outreach functional cost center) and other costs for individual client intake and counseling (screening, tracking, follow-up and case management functional cost center.) The goal of public information, education and outreach activities is to increase knowledge, attitudes, and behaviors in populations at the State/territorial/tribal and local levels. Costs in this category include media development and campaigns, public information materials development and printing, secondary educational messages, coalition and focus group support and travel, and group outreach and recruitment, such as through a speakers bureau presentation, church group activities, home health parties, or health circles.

D. Professional Education Functional Cost Center

Costs incurred to improve the education, training, and skills of health professionals, including allied health professionals, in the early detection and control of breast and cervical cancer fall into the professional education functional cost center. Professional education activities define gaps in the knowledge, attitudes, and practices (KAP) of health professionals and then develop mechanisms to improve the standards of practice. Costs in this category include conferences, workshops, and training for health professionals at the State/territorial/tribal and local level based on provider program participation or needs assessment. In addition, costs associated with professional newsletter and education materials development, printing, and

dissemination are considered appropriate when based on the needs assessment.

E. Quality Assurance and Improvement Functional Cost Center

Costs incurred to monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures fall into the quality assurance and improvement functional cost center. Quality assurance is defined by the following subcategories.

Breast— Programs will ensure the quality of any screening procedure for breast cancer and, in the case of mammography, will require American College of Radiology (ACR) accreditation and will recommend the following Food and Drug Administration (FDA) rules and regulations. Programs must meet the requirements of Public Law 102–539, the Mammography Quality Standards Act of 1992 (MQSA), most recently reauthorized and finalized October 31, 1998. Costs in this subcategory include the salaries of staff and the purchase of necessary equipment for inspection of mammography providers according to established standards of performance.

Cervical— Programs will ensure the quality of any screening procedure for cervical cancer and, in the case of the Pap test, will require Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) certification. Costs in this subcategory include the salaries of staff for the inspection of laboratories and the implementation of proficiency testing according to established standards of performance.

Provider Practice— Programs will ensure the quality of screening services by health care providers participating in the program through routine reviews and audits. Costs in this subcategory include the salaries of staff who review client charts, laboratory slips, and referrals to document accurate and appropriate client case management according to established protocols and guidelines.

F. Coalitions and Partnerships Functional Cost Center

Public Law 101-354 states that programs must coordinate services and activities funded through the cooperative agreement with other Federal, State/territorial/tribal and local breast and cervical cancer programs. Partnerships and coalitions are critical to implement a successful program to control breast and cervical cancers. The

involvement of a variety of committed partners, including health care organizations, social service, national and voluntary organizations, academia, and others will ensure the consideration of all aspects of breast and cervical cancer early detection in your program. Costs incurred with coalitions and partnerships fall into this cost center. These costs are usually minimal, because the joint efforts include all members sharing the workload and costs. Costs may include funds to support a limited number of paid administrative staff hours, copying, printing, coalition travel and supplies.

G. Surveillance and Evaluation Functional Cost Center

Costs incurred to evaluate activities under the functional cost centers through surveillance or program monitoring fall into this functional cost center. The program should develop a system to collect, edit, manage, and continuously improve the quality of data. Surveillance or program monitoring is defined by the following subcategories.

Surveillance— This subcategory includes costs for maintaining a surveillance system to obtain individual client data. Costs in this subcategory include the salaries of staff and the purchase of computer hardware, software, and programming to establish and maintain the surveillance system. This system is defined as follows:

- *Tracking*. Analysis of client data to ensure that women enrolled in the program receive timely and appropriate rescreening, diagnostic, and treatment services. Programs should distinguish between the collection of client data primarily for the direct provision of screening and follow-up services (Screening, Tracking, Follow-up, and Support Services Functional Cost Center) or primarily for the purposes of surveillance/program monitoring (Surveillance and Evaluation Functional Cost Center and/or Quality Assurance and Improvement Functional Cost Center).

- *Disease Burden.* Analysis of *aggregate* client data such as
  - Mortality— death certificates obtained from the State/territorial vital records office; and
  - Morbidity— population-based incidence obtained from the State/territorial cancer registry, and the National Cancer Institute's (NCI) Surveillance, Epidemiology and End Results (SEER) program.
- *Targeting and Utilization*. Analysis of *aggregate* population data such as
  - Behaviors— knowledge, attitudes, and practices obtained from Behavioral

Risk Factor Surveillance System (BRFSS) and KAP surveys; and

— Market penetration— effectiveness in reaching target populations from screening and census data.

C *Health Care System.* Assessing the health care system, including provider sites, health care professional personnel, and economic analyses.

Program Evaluation— Evaluation activities can be used for monitoring progress, assessing program effectiveness, and providing information for decision making and program management. Objectives should be developed that are specific, measurable, and defined by time for both the overall program and each program component. The status of program objectives should be measured through utilization of surveillance and other data. Costs associated with evaluation activities can range from informal assessments to routine data collection to formal assessments of specific program strategies. Costs in this subcategory also include the salaries of staff and the analysis of procedural reimbursements.

H. Framework for Determining 60 Percent/40 Percent Distribution

The table on the following page summarizes references in Public Law 101-354 and the Administrative Requirements and Guidelines. Program costs that are referenced in the Law are in the white columns, whereas items that are specified in the administrative requirements are in the lightly shaded columns. Most program expenses can be found in one of these four columns. The darkest shaded column includes a list of examples of costs that are not specifically addressed in the Law or the administrative requirements and are areas that are open for interpretation. The following questions are intended to help programs determine the appropriate category for those costs not specifically listed in the Law or guidelines. As of fiscal year 1999, client case management--as part of the essential support services provided to individual women--is clearly defined as part of the 60 percent distribution category.

I. Points To Consider in Determining the Classification of a Program Cost as Part of the 60 Percent Distribution Category

- Is the activity specifically included in the CDC Administrative Requirements?
- What is the intent of this activity? Example: Are you using a translator to help women communicate with their health provider at a screening site (60%), or are you using a translator to develop a new brochure (40%)?
- Is your justification for classifying this activity as a "Screening, Tracking, Follow-up or Support Services" activity consistent with this policy?
- What documentation is available to support this activity as a "Screening, Tracking, Follow-up or Support Services" activity?
  Example: Do you have staff timekeeping records or activity reports that can verify that a staff member's time is spent calling individual women for tracking and follow-up rather than for general data management activities?
- How would an auditor view your classification of this activity?
- How much of your budget is spent on activities that are clearly defined by law as a "Screening, Tracking, Follow-up or Support Services" activity (60%)?
- How much of your budget is spent on activities that are in "gray areas"?
- When applying for Federal funds in the future, will your use of current funds clearly indicate your ability to spend 60 percent of program funds on screening services?
- What are program funds actually paying for? Example: An outreach program is designed to train community volunteers to recruit individual women for screening. The final outcome is one-to-one outreach/recruitment, but the program funds are actually paying for training services (40%), not for the volunteers' costs to conduct one-to-one outreach (60%).
- Does the data management system serve primarily to retrospectively monitor and ensure the timeliness and adequacy of clinical services (40%) or does this system serve primarily to prompt case management/follow-up staff to contact individual women with abnormal screening results for referral and follow-up (60%)?

Framework for Determining 60 Percent/40 Percent Distribution

Law (60%)	*Guidelines (60%)*	*Interpretations*	*Guidelines (40%)*	*Law (40%)*
Screening Tests	**Screening Tests**	**Incentives**	**Public Education**	**Public Education**
Clinical Breast Exam	Office visits	**Data Entry**	Media	**Professional Education**
Mammography	Clinical supplies and Equipment		Materials development	**Quality Assurance**
Pelvic exam	**Diagnostic Tests**		Secondary education messages	**Evaluation**
Pap smear	Diagnostic mammogram		Coalition support/travel	**Surveillance**
Tracking, Follow-up and Support Services	Fine-needle aspiration		Focus groups	
Client case management	Ultrasound		Group outreach	
	Office visits		**Professional Education**	
	Cyst aspiration		Conferences	
	Colposcopy		Trainings/Newsletters	
	Colposcopy with biopsy		**Quality Assurance**	
	Endocervical curettage		Breast (ACR, MQSA)	
	Breast biopsy (excisional, core-needle, stereotactic)		Cervical (CLIA)	
	Surgical consult		Provider practice	
	Laboratory Fees		**Surveillance and Evaluation**	
	Tracking, Follow-up and Support Services		**-Surveillance**	
	Translation		- Tracking	
	Transportation		- Disease burden	
	1:1 Outreach		- Targeting	
	Client intake		Program evaluation	
	Client tracking		**All Other Functions**	
	Client counseling		Management & Planning	
			Administrative costs	

2. 10 Percent Administrative Costs

Public Law 101–354 requires programs to spend no more than 10 percent of the Federal monies for administrative expenses.

The basis for determining the 10 percent administrative cost is the total amount of Federal monies (financial assistance and direct assistance) awarded to the program. The administrative cost does not apply to the non-Federal matching funds. The 10 percent administrative costs will be considered part of the 40 percent of the budget used to support infrastructure activities.

The 10 percent limitation on administrative costs is in lieu of *indirect costs*. Each program may define the basis for its administrative costs. However, administrative expenses (i.e., indirect costs) associated with all contracts are considered part of the limitation placed on overall total administrative cost under the cooperative agreement award.

Calculation of 10 Percent Administrative Cost Maximum

Example

FA	2.9 M
DA	.1 M
Total	3.0 M

3.0 M x 10 percent	= 0.3 M (300,000)

3. Matching Funds

Matching funds refer to non-Federal resources (money and/or in-kind contributions) contributed by the program and its partners in the amount of $1 for each $3 of Federal money as required in Public Law 101–354 (see page I-12). Programs must identify, secure, ensure, and budget the resources and allowances of non-Federal contributions for the program. Official notification of the required amount of matching funds is provided to programs in the NCA issued by PGO.

The basis for determining this match is the total amount of Federal monies (financial assistance and direct assistance) awarded to the program. Programs must identify, secure,

ensure, and budget the sources and allowances of non-Federal contributions for the program.

Generally, if Federal monies are allowed for a service or activity, then non-Federal contributions for the same service or activity may be allowed as a source of matching funds for the program. Non-Federal contributions may be made directly or through donations from public or private entities. Contributions from private for-profit entities are allowable sources of matching funds.

Public Law 93-638 authorizes tribal organizations contracting under the authority of Title I and compacting under the authority of Title III to use funds received under the Indian Self-Determination Act as matching funds.

The types of contributions may be cash or in-kind, including equipment, services, or clinical services. Treatment, indirect, or overhead costs are disallowed as a source of matching funds. In addition, programs are restricted by maintenance of effort and Medicaid provisions in the law for determining the amount of their non-Federal contributions.

Calculation of Required Non-Federal Match

Example

FA	2.9 M	
DA	.1 M	
Total	3.0 M	
1:3 match = $\frac{3.0\ M}{3}$	= 1.0 M	(33 percent of FA & DA)
Total Approved Budget	4.0 M	
1:3 Match	1.0 M	(25 percent of total)

4. Maintenance of Effort

According to PL 101-352 (see page I-12), in determining the amount of non-Federal contributions to credit toward the matching funds requirement, the program can only use funds over and above the amount the program had contributed toward breast and cervical cancer programs and activities before the first fiscal year of Federal funding for this program. This baseline amount is calculated by taking the average for the two year period preceding the Federal funding. The Federal fiscal year is from October 1 through

September 30. For example, Federal fiscal year 1993 began on October 1, 1992, and ended on September 30, 1993. Thus, if a program was funded at the end of Federal fiscal year 1993 (i.e., September 30, 1993), the 2-year average period for maintenance of effort was from October 1, 1990, through September 30, 1992. The 2-year average amount is used as a program's baseline of previous contributions. Any non-Federal program contribution, above this baseline, can be counted as a source of match.

5. Medicaid as it relates to Maintenance of Effort or Match

Non-Federal Medicaid amounts, which are contributed by the program, are allowable as sources of match. However, the State Medicaid contribution is subject to the maintenance-of-effort requirement, must be program related, and cannot be used for any other program.

6. Medicare Reimbursements for screening and diagnostic services

Public Law 103–183 requires that the amount paid by a program to an entity for screening and follow-up services may not exceed the amount that would be paid under part B of Title XVIII of the Social Security Act (maximum Medicare rates in the State).

Programs will be required to comply with the maximum Medicare rates of the current Federal fiscal year when they begin to use the Federal funds awarded to them. This will allow programs maximum flexibility to plan and implement any changes in reimbursement rates when provider contracts are renewed.

Reimbursement rates for the breast and cervical cancer program may be consistent with the Medicare waiver approved by HCFA in the States with such a waiver. This would positively promote the participation of providers in the program and be more cost effective to implement.

For each of the screening and diagnostic services paid for by the CDC-funded breast and cervical cancer early detection program, providers may be reimbursed at a single rate determined by the program and within the range of regional Medicare rates approved by HCFA for the programs may also choose to reimburse for services using multiple rates, such as a single urban and a single rural rate or the various regional Medicare rates approved by HCFA.

However, programs must submit a plan to CDC for *prior approval* that outlines their proposed reimbursement rates for the breast and cervical cancer program before utilizing funds for screening and diagnostic services. This plan should include (1) all the HCFA-approved regional Medicare reimbursement rates within the State; (2) the reimbursement rate(s) proposed for the breast and cervical cancer program; (3) a justification or

explanation for the reimbursement rate(s), especially if the highest Medicare rates in the State are proposed for use; and (4) the projected date of implementation. This plan should include the information requested on the "Screening and Diagnostic Worksheet," estimating the number of women to be provided screening and diagnostic services during that budget period. (See Policy Section, “Reimbursement Policy for Screening and Diagnostic Services.” page IV-1)

7. Contracts

Public Law 101–354 allows programs to contract with public or non-profit private entities in carrying out programmatic activities. Public Law 103–183 allows programs to contract with for-profit private entities for screening and follow-up services. However, the amounts paid for screening and diagnostic procedures are not to exceed the Medicare reimbursement rates. Public Law 105- 340 and the amendments now allow programs to enter directly into contracts with private for-profit entities to provide screening **and non-screening** activities. However, if a non-profit entity and a for-profit entity compete for a contract and they are determined to be equally qualified, the program may give priority to the non-profit entity.

APPENDIX A: Guidelines for Budget Preparation

Introduction

Outlined below is the suggested format programs should use when submitting budget requests to the PGO for approval. Adopting this format will facilitate the review and approval of a budget by ensuring that the required information has been included in the request. In addition to providing the information below, programs must include a separate page outlining the distribution of each line item expenditure within the 60/40 distribution requirement. (See Attachment 3, page II-38, for a sample description)

A. Personnel

For each requested position, provide the following information: name of staff member occupying the position, if available; annual salary; percentage of time budgeted for this program; total months of salary budgeted; and, total salary requested. Identify the new positions (*) and previously approved but vacant positions requested.

Where possible, organize the list of requested positions by program component (e.g., program managers/administrative support staff, screening/tracking/follow-up/case management, public education, professional education, quality assurance and improvement, surveillance and evaluation, other). Also, provide a justification and describe the scope of responsibility for each new position, relating it to the accomplishment of program objectives.

Sample Budget

Personnel				**Total $_____**
Position Title and Name	Annual Salary	Time	Months	Amount Requested
Management/Administrative Support				
Project Manager John Doe	$45,000	100%	12 months	$45,000
Secretary Sandy Jones	$18,500	75%	12 months	$13,875
Screening/Referral/Follow-up				
Screening Coordinator Mary Smith	$31,000	100%	12 months	$31,000
Follow-up Coordinator (Vacant*)	$27,000	100%	12 months	$27,000
Public Education Staffing				
Health Education Specialist (Vacant)	$28,000	50%	12 months	$14,000

Sample Justification

See Attachment 1, page II-36, for sample justification of the new Follow-up Coordinator position.

B. Fringe Benefits

Fringe benefits are usually applicable to direct salaries and wages. Provide information on the rate of fringe benefits used and the basis for their calculation. If a fringe benefit rate is not used, itemize how the fringe benefit amount is computed.

Sample Budget

Fringe Benefits Total $_____

25% of _____ = Fringe Benefits
Total salaries

If fringe benefits are not computed by using a percentage of salaries, itemize how the amount is determined.

Example:	Project Coordinator — Salary		$45,000
	Retirement 5% of $45,000	=	$2,250
	FICA 7.65% of $45,000	=	3,443
	Insurance	=	2,000
	Workers' Compensation	=	_____
		Total:	

C. Travel

Funds requested in the travel category should be for staff travel only. Travel for consultants should be shown in the consultant category. Travel for coalition members and advisory committees should be itemized in the same way specified below and placed in the "Other" category.

In-State Travel—Provide a narrative justification describing the travel staff members will undertake. List where travel will be undertaken, number of trips planned, who will be making the trip, and approximate dates. If mileage is to be paid, provide the number of miles and the cost per mile. If travel is by air, provide the estimated cost of airfare. If per diem/lodging is to be paid, indicate the number of days and amount of daily per diem as well as the number of nights and estimated cost of lodging. Include the cost of ground transportation when applicable.

Out-of-State Travel—Provide a narrative justification describing the same information requested above. Include the out-of-State trips requested by CDC in the continuation application guidance.

Sample Budget

Travel (In-State and Out-of-State) Total $_____

In-State Travel:

1 trip x 2 people x 500 miles r/t x .27/mile	=	$ 270
2 days per diem x $37/day x 2 people	=	148
1 nights lodging x $67/night x 2 people	=	134
25 trips x 1 person x 300 miles avg. x .27/mile	=	2,025
	Total	$2,577

Sample Justification

The Project Coordinator and the Health Education Specialist will travel to (location) to provide orientation to mammography providers. The Project Coordinator will make an estimated 25 trips to local health departments and screening sites to monitor program implementation.

Sample Budget

Out-of-State Travel:

1 trip x 1 person x $500 r/t airfare	=	$500
3 days per diem x $45/day x 1 person	=	135
1 night's lodging x $88/night x 1 person	=	88
Ground transportation 1 person	=	50
Total		$773

Sample Justification

The Project Coordinator will travel to CDC, in Atlanta, GA, to attend the NBCCEDP Program Director's meeting.

D. Equipment

Provide justification for the use of each item and relate it to specific program objectives. Equipment is defined as an article of tangible, nonexpendable, personal property having a useful life of more than 1 year and an acquisition cost of *$5,000 or more per unit*. (See PHS Policy Statement, page 2–1, 2–2.). Items that cost less than $5,000 per unit should be included in the "Supplies" category. Maintenance or rental fees for equipment should be shown in the "Other" category.

Sample Budget

Equipment			Total $_____
			Unit Cost
	Item A =		5,378
	Item B =		6,860
	Item C =		15,028
		Total	$ 27,266

Sample Justification

Given the high unit cost, provide complete justification for all requested equipment, including a description of how it will be used in the program (Program Objective XX), the volume of projected use (if relevant, such as number of additional tests annually), who will use it (which organizational unit, such as State laboratory), why it is needed, and why the purchase of it is essential and more advantageous than renting or obtaining access to it through other means (e.g., contracting with a provider for services). The source of estimated cost for each unit of equipment requested should be included in the justification.

E. Supplies

Individually list each item requested. Show the unit cost of each item, number needed, and total amount. Provide justification for each item and relate it to specific program objectives. It is recommended that when training materials are kept on hand as a supply item, they be included in the "Supplies"' category. When training materials (e.g., pamphlets, notebooks, videos, other handouts) are ordered for specific training activities, these items should be itemized and shown in the "Other" category. If appropriate, general office supplies may be shown by an estimated amount per month times the number of months in the budget category.

Sample Budget

Supplies		Total $_____
General office supplies (pens, pencils, paper, etc.) 12 months x $240/year x 10 staff	=	$2,400
Education pamphlets (3,000 copies @) $1 each	=	$3,000
Educational videos (10 copies @ $150 each)	=	$1,500
Personal computer (@ $4,500—specify type)	=	$4,500
Word processing software (@ $400—specify type)	=	$ 400

Sample Justification

General office supplies will be used by staff members to carry out daily activities of the program. The education pamphlets, XXX, will be purchased from XXX and used to illustrate and promote breast self-exams among women in the program (Public Education Objective XXX). The educational videos, XXX, will be purchased from XXX and added to the lending library for the use of radiology technologists in the program (Professional Education Objective XXX). Use of this video will help to update their knowledge and skills in the proper positioning of women for mammography tests. The personal computer will be assigned to the new health educator position (Public Education Objective XXX).

F. Contractual

Cooperative agreement recipients must obtain written approval from CDC *prior to* establishing a third-party contract to perform program activities. Approval to initiate program activities through the services of a contractor requires submission of the following information to CDC's PGO:

Screening Contracts Total $_____

Screening contracts as used here refer to "generic" contracts used to secure the services of multiple providers/contractors (e.g., screening clinic contracts, mammography facility contracts, laboratory contracts).

Continuation Screening Contracts: Provide in table format the names of each screening provider (contractor) previously approved by CDC who will continue participation in the program. For each provider, specify the number of women to be screened or procedures to be completed (e.g., number of mammograms), total amount budgeted, and period of performance. If it varies, group the listing of providers by their period of performance.

New Screening Contracts: Separately, list the above budget information for each new screening provider (contractor) to be awarded a contract.

The total amount allocated for screening services should be equal to those costs appearing on the Screening and Diagnostic Worksheet (See Program Policies section, "Reimbursement Policies for Screening and Diagnostic Services," page IV-1)

Non-screening Contracts Total $_____

Non-screening contracts as used here refer to individual contracts with various entities for activities, such as the development of media campaigns, design and implementation of surveys or special studies (e.g., evaluation), development of program materials, or similar program activities.

For each non-screening contract, provide an itemized budget and justification related to program objectives. Include personnel salaries, fringe benefits, travel, equipment, supplies, other direct costs, and indirect costs, as appropriate.

Sample Budget

Contracts* Total $_____

Summary of Contract Requests

Continuation Contracts

Total Continuation Screening Contracts		**$ Amount**
(generic contract, 150 contractors)		
Name of Contractor	$ Amount	
Name of Contractor	$ Amount	
Total Continuation Non-Screening Contracts		**$ Amount**
Name of Contractor	$ Amount	

New Contracts

Total New Screening Contracts		**$ Amount**
Name of Contractor	$ Amount	
Total New Non-Screening Contracts		**$ Amount**
Name of Contractor	$ Amount	

* See "Screening and Diagnostic Worksheet" for estimates of projected screening and diagnostic procedures and costs

Sample Justification

All new and continuation contracts require prior approval from CDC annually. Submit the following required information for each contract:

- **Name of Contractor**: Identify the name of the proposed contractor.

- **Method of Selection:** Indicate whether the contract is sole source or competitive bid. Describe the qualifications of the contractor. In addition, identify whether the contractor is a private for-profit organization.

- **Period of Performance:** Specify the beginning and ending dates of the contract. Additionally, indicate whether this is a new or continuation contract.

- **Scope of Work:** Describe in outcome terms, the specific services/tasks to be performed by the contractor as related to the accomplishment of program objectives (e.g., screen 250 women aged50 years and older for breast and cervical cancers. Deliverables (e.g., development of a curriculum, design of a survey questionnaire) should be clearly defined.

For screening services where multiple providers have the same contract, only a single description of the required information is needed. A copy of the actual or individual contracts should not be sent to CDC.

- **Method of Accountability:** Describe how the progress and performance of the contractor will be monitored during and on close of the contract period. Identify who will be responsible for supervising the contract. In addition, for continuation contracts, describe their previous performance.

- **Itemized Budget and Justification:** Provide an itemized budget with appropriate justification. See "Sample Budget" below. If applicable, include any indirect cost paid under the contract and the indirect cost rate used.

More detailed information is described in the *PHS Grants Policy/Statement* (POSTAWARD ADMINISTRATION, Contracts for Substantive Programmatic Work, pg B-16 to B-18 [Revised 9/l/91]), included in the Reference section of this Manual.

If the above information is unknown for any contractor at the time the application is submitted, the information may be submitted at a later date as a revision to the budget. In situations where a generic contract is used for multiple contractors (e.g., screening providers), a complete description of the required information should be submitted for approval along with a list of individual contractors to which it applies. Copies of the actual contracts should not be sent to CDC. In the body of the budget request, a summary should be provided of the proposed contracts and amounts for each.

G. Consultant

This category is appropriate when hiring an individual to give professional advice or services (e.g., training, expert consultant, etc.) for a fee but not as an employee of the grantee organization. Written approval must be obtained from CDC *prior to* establishing a written agreement for consultant services. Approval to initiate program activities through the services of a consultant requires submission of the following information to CDC:

Sample Budget

Consultant		Total $_____
Summary of Consultant Requests		
Continuation Consultant Contracts		
Name of Consultant	$ Amount	
Name of Consultant	$ Amount	
New Consultant Contracts		
Name of Consultant	$ Amount	

Sample Justification

This category is appropriate when hiring an individual who gives professional advice or provides services for a fee and who is not an employee of the grantee organization. All consultants require prior approval from CDC annually. Submit the following required information for consultants:

- **Name of Consultant:** Identify the name of the consultant and describe his or her qualifications.
- **Organizational Affiliation:** Identify the organizational filiation of the consultant, if applicable.
- **Nature of Services To Be Rendered:** Describe in outcome terms the consultation to be provided, including the specific tasks to be completed and specific deliverables. A copy of the actual consultant agreement should not be sent to CDC.
- **Relevance of Service to the Project:** Describe how the consultant services relate to the accomplishment of specific program objectives.
- **Number of Days of Consultation:** Specify the total number of days of consultation.

- **Expected Rate of Compensation:** See "Sample Budget", above. Specify the rate of compensation for the consultant (e.g., rate per hour, rate per day). Include a budget showing other costs such as travel, per diem, and supplies.

- **Method of Accountability:** Describe how the progress and performance of the consultant will be monitored. Identify who is responsible for supervising the consultant agreement. In addition, for continuation consultants, describe their previous performance.

If the above information is unknown for any consultant at the time the application is submitted, the information may be submitted at a later date as a revision to the budget. In the body of the budget request, a summary should be provided of the proposed consultants and amounts for each.

H. Other

This category contains items not included in the previous budget categories. Individually list each item requested and provide appropriate justification related to the program objectives.

Administrative costs are allowed in lieu of indirect costs and may not exceed 10 percent of the total financial assistance and direct assistance awarded. Where administrative costs are used in other Federal grants and cooperative agreements, it is recommended that the program use the same definition for consistency. (See page II-19 for additional information and formula calculation).

Sample Budget

Other	Total $_____
Telephone ($ ___ per month x ___ months x #staff)	= $ Subtotal
Postage ($ ___ per month x ___ months x #staff)	= $ Subtotal
Printing ($ ___ per x ___ documents)	= $ Subtotal
Equipment Rental (describe) ($ ___ per month x ___ months)	= $ Subtotal
Publication (conference handout, describe)	= $ Subtotal
Coalition Travel (see travel category for justification details requested)	= $ Subtotal
Program Administrative Costs	= $ Subtotal

Sample Justification
Some items are self-explanatory (telephone, postage, rent), unless the unit rate or total amount requested is excessive.

If not, include additional justification. For printing costs, identify the types and number of copies of documents to be printed (e.g., procedure manuals, annual reports, materials for media campaign). Also, see explanation under "Supplies" regarding materials for specific trainings.

I. Total Direct Charges **Total $_____**

J. Non-Federal Matching Fund Requirement

Non-Federal matching funds in the amount of $1 for every $3 Federal funds awarded is required for the comprehensive screening programs. The details of this requirement are described separately and are available. Projected sources and amounts of non-Federal matching funds in the forthcoming budget year should be included with the proposed budget.

Non-Federal Cash Resources and Amounts (Examples): Provide details on each source.

- Program appropriations for screening, tracking, and follow-up;
- State Medicaid for breast and cervical cancer screening (above maintenance of effort);
- State tobacco tax revenue
- Cash donations (please list each contributor and the dollar amount); and,
- Community fund-raising (please list each event and the amount raised).

Non-Federal Non-Cash Resources and Amounts (Examples): Please provide an itemized breakdown for each source to demonstrate how you arrived at the total for that source.

- Donated vehicles and equipment (e.g., vans for transportation, laboratory equipment, computers);
- Donated services (e.g., screening tests, diagnostic tests, transportation,volunteer time, ACS, YWCA. If using the difference between the Medicare rate and the usual and customary provider charge, document how the usual and customary charge was determined.See Attachment 2 for additional guidance.) ;
- Donated supplies (e.g., education materials, promotional materials);
- Donated media time (e.g., television, radio, print); and,
- Donated professional time (e.g., service on coalitions, advisory committees, advertising/marketing consultation).

(See Budget Attachment 2, page II-37, and page II-19 for additional information and formula calculation).

K. Maintenance of Effort

List amount of contributions made by the program toward the breast and cervical cancer programs 2 years prior to comprehensive funding. See page II-20 for additional information.

L. Description of 60/40 Distribution Requirement

(See Attachment 3, page II-38, and pages II-10 through II-18 for additional information and guidance).

Please be sure to double check your budget calculations. Errors in budget calculations can result in awards that do not match program requirements.

Attachment 1: Sample Justification—New Personnel

The format may vary, but the description of responsibilities should be directly related to specific program objectives. Once the position has been filled, a copy of the new employee's resume, with a letter requesting approval of the position, if previously restricted, should be sent to PGO.

Job Description: Follow-up Coordinator (Name)

The Follow-up Coordinator is responsible for ensuring that women with suspicious or abnormal screening results receive appropriate diagnostic follow-up and treatment in a timely manner. The person in this position will:

- Review the program data bimonthly to identify and facilitate individual follow-up for women who need it; directly contact providers to ascertain the status of patient follow-up and aggressively intervene to facilitate accomplishment of this when necessary; and maintain program-level documentation of attempts to reach women and their refusal of follow-up care when this occurs.
- Facilitate the timely, accurate, and complete reporting of patient data to the program tracking system; review aggregate data quarterly to monitor the achievement of program objectives; and prepare quarterly reports for CDC.
- Develop creative strategies and incentives to identify and encourage providers to donate diagnostic and treatment services not covered by the program; facilitate the development of community-based referral systems, including medical and social service providers and the participation of appropriate voluntary organizations; and facilitate the effective utilization of community-based coalitions to identify local providers and encourage their participation.
- Assist the program's medical advisory committee to develop clinical follow-up protocols for women with suspicious or abnormal screening and diagnostic results; facilitate the responses to providers on clinical questions asked; and provide ongoing training and consultation to providers regarding appropriate referral and follow-up based on the program protocols.
- Assist in monitoring of providers through site visits to ensure appropriate and timely referral and follow-up of women based on program protocols.

Attachment 2: Sources and Projections of Matching Funds

SAMPLE
Summary of Clinical Expenditures by Fiscal Year

Fiscal Year	Date of Service	Total # of Women Served[1]	Total # of Screens/Office Visits[2]	Total # of Diagnostic Procedures[3]	Total Usual & Customary Fee - **Identify Source**	Total Actual Paid (Medicare Rate)	Total Differential (Match Contribution)
Year 5	10/1/98 - 9/30/99						
Year 4	10/1/97 - 9/30/98						
Year 3	10/1/96 - 9/30/97						
Year 2	10/1/95 - 9/30/96						
Year 1	10/1/94 - 9/30/95						
Totals							

[1] Women should only be counted once within a Fiscal Year.

[2] Should include Office Visits,Pap Smears, and Initial Mammograms provided within a Fiscal Year.

[3] Should include all breast and cervical diagnostic procedures provided within a Fiscal Year.

Attachment 3: Sample Description of 60/40 Distribution Requirement

Source	**Total**	**60%**	**40%**
Project Director	$45,000		$45,000
Epidemiologist	$60,000		$60,000
Data Manager	$36,000		$36,000
Clerk Typist II	$23,000		$23,000
Nurse Consultant	$40,000	$40,000	
Total Personnel	**$214,000**	**$40,000**	**$174,000**
Fringe Benefits @ 25%	**$53,500**	**$10,000**	**$43,500**
Travel	**$24,000**		**$24,000**
Equipment	**0**		**0**
Supplies	**$30,000**		**$30,000**
Contracts	**$1,965,000**	**$1,540,000**	**$425,000**
Screening Contracts	1,790,000	1,540,000	$250,000
Non Screening Contracts	$45,000		$45,000
Data Management	$110,000		$110,000
Training	$10,000		$10,000
Medical Consultant	$10,000		$10,000
Essential Screening Support Services	$10,000	$10,000	
Other	**$284,750**		**$284,750**
Postage	$6,000		$6,000
Printing	$12,000		$12,000
Telephone	$3,000		$3,000
Coalition Travel	$30,000		$30,000
Administrative Costs (#10%)	$233,750		$233,750
Total Budget	**$2,571,250**	**$1,600,000**	**$971,250**
Actual Percent of Budget	100%	62%	38%

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Appendix A: Program Progress Indicators III-3

Introduction

The scope of the program management responsibilities for implementing the NBCCEDP is extensive given the amount of oversight and guidance required at all levels of program implementation. Three tools have been developed to assess the infrastructure development and service delivery components of the NBCCEDP: the System for Technical Assistance Reporting (STAR), the Minimum Data Elements (MDE), and the Program Progress Indicators.

The guidance contained in this section of the manual highlights the electronic reporting systems that collect information on screening, management and infrastructure development activities, briefly describes the data elements that are necessary to assess program progress, and outlines the program progress performance indicators used by CDC. For additional information on the framework and strategies to manage the NBCCEDP, refer to the 3-ring binder previously distributed, entitled "Program Guidelines for Breast and Cervical Cancer Early Detection 1997."

System for Technical Assistance Reporting (STAR)

STAR is a technical assistance tool that was designed to collect and report data on the management and infrastructure components of the NBCCEDP National Breast and Cervical Cancer Early Detection Program. STAR has replaced the lengthy narrative quarterly reports and is submitted to CDC once a year. NBCCEDP-sponsored programs provide CDC with information on management, screening support activities, public information and education, recruitment and outreach, professional education, quality assurance and improvement, and coalitions and partnership development. STAR is a Microsoft Windows-based application and is comprised of three main components: Data Entry, Reports, and Utilities. Please refer to the "Guide to Using STAR Version 2.0" for further guidance on using STAR and submission requirements.

Minimum Data Elements (MDE)

The MDE's are a set of standardized data elements developed to ensure that consistent and complete information on screening location, patient demographic characteristics, screening results, diagnostic procedures, tracking and follow-up, and treatment information are collected on women screened and/or diagnosed with NBCCEDP funds. These are the data items that are minimally necessary for NBCCEDP-sponsored Programs and the CDC to monitor clinical outcomes. Programs are encouraged to collect additional data for program management purposes. The MDE's are collected for each woman, computerized, converted into a standardized format, and transmitted to our data contractor, Information Management Systems (IMS). Please refer to the "Data User's Manual Version 4.1" for additional guidance on the

MDE's and submission requirements.

Program Progress Indicators

The Program Progress Indicators("Indicators") have been developed to provide a systematic approach for rapid assessment of program progress. Indicators are not intended to serve as a comprehensive assessment of a Program; rather indicators provide a shapshot that can serve as an "early detection system" for potential problems and as a way to track a program's improvements over time. Three key program areas are included in the Program Progress Indicators: Program and Fiscal Management; Infrastructure; and Service Delivery.

Program Progress Indicators change from time to time to reflect emerging priorities of the NBCCEDP. The Indicators intentionally highlight program areas where there is variability among programs to allow identification of "better practices" as well as to alert programs to potential problems as early as possible. Stakeholders such as Program Directors and CDC staff participate in the process of devising new indicators. Indicators are used by CDC to guide development of new policies, training, and technical assistance. In addition, they are useed as part of the process of allocating cooperative agreement funds and the assignments of Public Health Advisors in the field.

Appendix A contains the Program Progress Indicators for FY 2001. For each Indicator, the following are provided: short title; rationale; method for determining a raw score; data source; either a performance goal or minimum standard for performance; and references. Each Indicator calculation produces a raw score that can be interpreted according to the performance goal or minimum standard. In some cases, a higher score is desirable (e.g., indicator for utilization of funds to minimize unobligated funds) and in some cases, a lower score is desirable (e.g., inidcator which examines the MDE error rate). Because of this, the indicator scores should NOT be added together. Rather, each indicator should be interpreted individually as an indication of performance in a specific program area.

The Indicators supplement NBCCEDP's overall efforts to monitor, assess, and guide Programs. Other evaluation and oversight activities such as site visits, review of annual work plans, semi-annual data reviews, and audits continue to be important in ensuring the success of the NBCCEDP. In addition, CDC provides guidance on many issues in many different forms. Programs are expected to pursue important goals and strategies in addition to those that are reflected in the current set of Program Progress Indicators.

National Breast and Cervical Cancer Early Detection Program

Program Progress Indicators: Fiscal Year 2001

Background

Throughout its 10-year history, the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) has supported program evaluation in order to monitor, assess, and guide the operations of NBCCEDP cooperative agreement recipients (Programs). This has been accomplished through several channels including: (1) monitoring budget and expenditure information; (2) routine review of Minimum Data Elements, including summaries such as the Data Quality Indicator Guide and Management Report; (3) assessments of annual work plans submitted to CDC with applications for funding; (4) review of quarterly or semi-annual progress reports submitted by Programs; and (5) site visits, technical assistance, and training.

By 1997, the NBCCEDP had grown to include comprehensive breast and cervical cancer screening programs in all 50 States, five U.S. territories, and the District of Columbia; and by 1999, also included 15 American Indian/Alaskan Native Tribes and Tribal organizations. NBCCEDP funding allocations are based on Program need, capacity, and performance as well as the overall amount of resources available for the NBCCEDP. In light of the increasing size and complexity of NBCCEDP, CDC identified the need for an integrated, practical, and systematic approach to assessing program performance to inform decisions for resource allocation. Equally important was the development of an "early detection system" for potential problems, especially problems related to the timeliness and adequacy of screening and diagnostic services provided through NBCCEDP. Additionally, Programs had requested guidance from CDC in identifying key issues upon which to focus their attention for program development, management, and improvement.

Development of Progress Indicators and Policy

In 1997, CDC conducted a preliminary analysis of the feasibility of using a set of qualitative and quantitative measures to assess Program performance. CDC staff developed a set of 10 measures to rate Programs on a scale of 0-10 points each in areas such as budget management; the adequacy of Program policies and procedures; and performance in outreach, screening service delivery, and recruitment of women aged 50 and older. Ratings were based on the professional judgment of CDC staff and on data such as screening levels obtained from MDE data. Although these measures provided a general assessment of program performance, the nature of the measures did not allow for standardization and were of limited use. However,

systematic assessment by use of indicators was found to be a helpful process. Therefore, in 1998, a work group of CDC staff was formed to study the issue and to develop a set of Program Progress Indicators (Indicators) based primarily on standardized measures and quantitative data. In December, 1998, a draft of the Indicators was shared with Program Directors who provided feedback and suggestions for further refinements. An official policy including the text of the 1999 Indicators was issued in March, 1999 as part of the NBCCEDP Policies and Procedures Manual.

The 1999 Indicators have been used for a variety of programmatic and management purposes including: informing CDC funding decisions; identifying Programs' needs for CDC guidance; providing information useful to CDC in planning, policy development, training, and technical assistance; drawing attention to apparent "better practices" in the field; and providing a systematic and consistent approach to assessing Program progress during site visits. During the 1999 budget cycle, data limitations included data lag time and unavailability of data for recently-funded programs; however, these issues are expected to be resolved by the 2000 budget cycle.

Feedback Regarding 1999 Performance Indicators

Several positive outcomes from the 1999 budget process support the continued use of a system of Indicators for NBCCEDP. Several Program Directors reported to CDC Program Consultants that they were pleased with the overall concept of a system of performance monitoring and measurement. Some Program Directors commented that the Indicators provided clarity on CDC's expectations, helping Programs to focus their program evaluation and quality improvement efforts. Others believed that the use of Indicators made it more likely that good performance would be noted and rewarded.

For CDC staff, the Indicators provided an organized method for reviewing the progress of Programs, helping to pinpoint apparent Program strengths and shortcomings. When there was a discrepancy between the Indicators score and Program Consultant's perception of a Program's performance, the Indicators served as a useful basis for further discussion and clarification. PSB staff commented that this systematic approach fostered a sense of fairness and consistency which was helpful to them in discussions with Programs of performance measurement and budget decisions. The CDC management team expressed that the Indicators were likewise helpful to them in informing and documenting budget decisions.

Lessons Learned

In 1999, CDC also completed a review of the relevant literature on performance measurement in the fields of public administration and public program management. From this review and from feedback received from Programs and from CDC staff, the following recommendations were developed. Included in each paragraph is CDC's action step responsive to the recommendation.

A. Limit the number of indicators to no more than 15. Experts in the field of management and performance indicators recommend that the number of indicators should be appropriate to the organization and its diversity. A common mistake in the use of performance indicators is to use excessive numbers of indicators, resulting in an "information-overload." To retain impact and value, indicators should be structured as *indicators* of progress rather than a comprehensive set of measures of all aspects of a program. Indicators should be limited to a small, relevant set. CDC Action Step: The NBCCEDP Indicators for 2001 consists of 11 measures.

B. Provide adequate monitoring for aspects of Program performance and quality not easily measured by indicators. Indicators cannot substitute for ongoing assessment of program performance, quality, and need. Site visits, comprehensive data reviews, MDE data audits, financial audits, and other assessments of performance continue to be important to adequately assess Program quality, efficiency, and effectiveness.CDC Action Step: Programs continue to receive feedback in a variety of ways including site visit reports, technical assistance telephone conferences, MDE data conference calls, data audits, and informal discussions.

C. Engage stakeholders in development and use of Indicators. Indicators should measure areas considered important and relevant to Program staff as well as to CDC. Stakeholder involvement in developing and using Indicators will help foster a sense of ownership and commitment to the process. Program stakeholders can also provide a realistic assessment of the practicality of data collection and interpretation for each Indicator. CDC Action Step: CDC continues to engage stakeholders in the development of Indicators, providing opportunities for feedback and suggestions at Program Directors'Meetings, as well as inviting written and verbal feedback throughout the year.

D. Stress the importance of timely, appropriate, and useful feedback to Programs. Experts in the field of public management agree that follow-up gives credibility to the process of using performance indicators. A lack of feedback often contributes to a disinterest not only in indicators but in performance itself. Negative-only feedback can foster attempts to "make things look good on paper." CDC Action Step: As a feedback mechanism, CDC Program Consultants now routinely prepare a summary of a Program's performance on each Indicator and include a discussion of performance Indicators as part of site visits. Programs are encouraged to track their own progress.

E. Indicators should be used as guidance, not as a sole basis, for allocating resources. Since the beginning of the NBCCEDP, budget decisions have been based on three general criteria: (1) need; (2) capacity; and (3) performance. Indicators are helpful in characterizing program performance and are used in concert with other assessments of performance such as MDEs, site visits, and review of progress reports. Need and capacity are also assessed by a variety of methods and information. CDC Action Step: CDC

continues to use an integrated approach to resource allocation which reflects a balance of programmatic and policy goals.

F. Include Indicators from all key program areas such as operational, financial, and service measures. While it is tempting to select Indicators for which quantitative measures are easily available (such as measures of service delivery), a balanced approach is necessary to ensure that management systems and infrastructure adequately support service delivery. Quantitative measures provide a sense of objectivity and consistency; however, qualitative assessments can be successfully integrated when expectations are clear about what is being assessed and the basis for assessment. CDC Action Step: The 2001 Indicators include measures for operations, financial management, and service delivery. Proposed indicators for 2002 include both qualitative and quantitative measures.

G. Update Indicators periodically to ensure that they measure aspects of Programs that are relevant, important, and timely. In education, public schools which use performance indicators often encounter the problem of "teaching to the test," where teachers excessively focus on the skills their students need to score well on standardized tests rather than teaching a comprehensive set of skills. Experts advise that changing performance indicators discourages the manipulation of data to achieve a high score on a particular measure. CDC Action Step: The 2001 Indicators were revised from the 1999 Indicators to reflect current priorities. New indicators will be added in 2002 and 2003 to emphasize emerging priorities.

H. Ensure that Indicators are consistent with the NBCCEDP mission. Indicators should be reviewed in light of emerging goals and priorities of the NBCCEDP, relevant to the accomplishment of long-term goals, and consistent with the NBCCEDP mission. CDC Action Step: Feedback from Programs will help ensure that the Indicators correctly reflect current NBCCEDP priority areas.

Fiscal Year 2001 Indicators

The attached set of Indicators for Fiscal Year builds upon previous work while addressing new priority areas. The Indicators intentionally highlight program areas where there is variability among programs. This is important in helping to alert Programs to potential problems as early as possible as well as to identify "better practices" in various program areas.

For each Indicator, the following are provided: short title; a rationale for inclusion; a method for calculating the Indicator; the data source; either a performance goal or minimum standard for performance; and references. Each indicator calculation produces a raw score that can be interpreted according to the performance goal or standard for the indicator. In some cases, a higher score is desirable (e.g. indicator A-2 Minimization of Unobligated Funds) and in some cases a lower score is desirable (e.g. indicator B-1, which examines the MDE Error Rate.)

Because of this, the indicator scores should not be added together, but rather each should be interpreted individually as an indicator of performance in a specific program area. This set of Indicators attempts to incorporate lessons learned as well as emerging priorities for NBCCEDP. The Indicators are organized into three major categories which reflect key components of a Program. Each category is briefly described below.

1. Program and Fiscal Management. This category reflects Program performance in the areas of planning, organizing, directing, coordinating, managing and budgeting. Indicators in this category help characterize the success of the Program in meeting fiscal requirements, implementing service delivery as planned, and making realistic projections of the type and level of Program activities that can be accomplished in a budget year. Poor scores on Indicators in this category suggest a possible need for improved planning, more realistic budget projections, better management of unobligated funds, or an adjustment of the level of Program activity. Poor scores may also suggest a need for increased activity in specific areas, such as targeted outreach to meet planned levels of service delivery.

2. Infrastructure. Sufficient staff and adequate supporting systems such as a data management system are essential elements of a successful Program. Within NBCCEDP, Programs are structured in a variety of ways. For example, some Programs rely on contractors for an array of Program activities while other Programs work within a health department clinic model. No matter what program structure is used, the basic infrastructure needed to support a service-delivery program includes data management, staffing, and evaluation. Two of these areas are highlighted in the Indicators for 2001 and reflect the operating systems which support day-to-day program implementation and efforts in quality improvements. An indicator for evaluation capacity is planned for 2002. These indicators can help to pinpoint potential problem areas and identify opportunities for further program improvements.

3. Service Delivery. The 2001 Indicators for Service Delivery highlight three critical clinical areas: client tracking, timeliness of diagnosis, and timeliness of treatment. Screening tests for cancer detection are of little use unless women with abnormal screening results receive prompt and appropriate diagnostic services, and women with cancer receive prompt and appropriate treatment. CDC is strongly committed to ensuring that women receive high-quality services that meet or exceed the clinical standards and guidelines set by NBCCEDP. Systems that ensure test results are promptly interpreted and diagnostic services are received when needed support the overall mission of NBCCEDP to reduce cancer morbidity and mortality. CDC continues to aggressively pursue the goal of ensuring that women who need diagnostic and treatment services receive them in a timely manner. Poor scores indicate the need for further investigation–first to ensure that all women have received the services they need; and secondly to determine what system-level improvements can be made to support improved performance in this area.

For each indicator, a time period to be considered is also identified. For example, in the Service Delivery category, data are based on an average of the most recent 24 months. This approach provides incentives for Programs to work toward improved scores, since poor performance from years past will not obscure evidence of performance improvements over time. In addition, feedback based on a 24-month period is more sensitive to changes than cumulative data. Thus, Indicators with short time frames better reflect current Program performance and allow early identification of potential problems that may be developing.

CDC use of program progress indicators is an ongoing process intended to support program improvements important to the continuing success of NBCCEDP. At the October, 2000 meeting of the Program Directors for NBCCEDP, comments and suggestions were invited on a prior draft of this document. Comments were received and many were incorporated into the final version of this guidance document.

A copy of the bibliography for the literature review described in this summary is available on request from Diane Dunet (email: ddunet@cdc.gov).

Summary of NBCCEDP Program Progress Indicators for Fiscal Year 2001

A. Program and Fiscal Management

A-1. Percent of Funds Allocated for Screening and Diagnostic Tests
Proportion of budget allocated to screening and diagnostic tests serves as an indication (but not a direct measure) of whether a program is likely to be within the 60/40 requirement. This reflects program and fiscal management.

A-2. Attainment of Target Level of Screening
Projected number of client services submitted with budget request is compared to the number of services actually delivered. This reflects planning, implementation, and ongoing program management.

A-3. Minimization of Unobligated or Carry-over funds
Funds awarded to program are compared to the funds spent. This serves as an indication of ongoing fiscal and program management.

B. Infrastructure

B-1. Data Management: Cumulative error rates for the Minimum Data Elements are tracked over a 24-month period. This reflects data management as well as data system performance.

B-2. Staffing: Staff positions requested in budget but remaining vacant for 6 months or longer are tracked. Having key staff positions filled is an indication of whether a Program has the needed infrastructure to manage and implement a program.

C. Service Delivery

C-1&2. Tracking Abnormal Test Results (breast and cervical calculated separately)
Completeness of program records (those showing a final diagnosis for all women with abnormal screening results) is tracked. This reflects the performance of tracking system, data collection arrangements, and service delivery system.

C-3&4. Ensuring Timeliness of Diagnosis (breast and cervical calculated separately)
The proportion of women who do not receive a final diagnosis within 60 days of an abnormal screening test result is tracked. This reflects the performance of service delivery system, data collection arrangements, and client followup systems.

C-5&6. Ensuring Timeliness of Treatment (breast and cervical calculated separately)
The proportion of women who do not have treatment initiated within 60 days of a diagnosis of cancer is tracked. This reflects the performance of service delivery system, data collection arrangements, and client followup systems.

A. Program Management and Fiscal Management

A-1	**Percent of Funds Allocated for Screening and Diagnostic Tests**
Rationale	Management of and accountability for federal funds continue to be important NBCCEDP priorities. The proportion of funds a Program allocates for screening and diagnostic tests is a strong *indication* of whether Programs are *likely* to be able to meet the 60/40 requirement. This indicator does NOT directly measure 60/40 compliance since some other services (such as case management) are allowable in the 60% category. However, Indicator A-1 serves as useful feedback showing an important part of how program funds are allocated. If the percentage allocated for screening and diagnostic tests is low, program priorities may need adjustment.
Calculation	$\frac{\text{Total dollar amount for screening tests and diagnostic services* (}\underline{\textit{Excluding}\text{ ancillary screening, referral and followup services, etc}}\text{)}}{\text{Total dollar amount of CDC award}} \times 100$ *Note: Although ancillary services may be allowed in the 60% calculation for budget purposes, Indicator A-1 looks at *one part* of the activities included in the 60% portion of the budget. A-1 is NOT intended to be a comprehensive measure of 60/40.
Data Sources	<u>Total dollar amount for screening and diagnostic services</u>: Final Screening and Diagnostic Services Worksheet. When a final award amount is different than requested budget amount, Programs submit a revised Screening and Diagnostic Services Worksheet with a revised work plan. <u>Dollar amount of CDC award:</u> CDC Notice of Grant Award
Performance Goal	A goal for this ratio *per se* has not been established. However NBCCEDP program guidelines provide that 60% or more of expended funds are used to pay for screening tests, diagnostic services, lab fees, and essential screening support services including tracking, followup services, case management, etc. (See Policies and Procedures Manual, II-18, columns 1 and 2.)
References	A. Legislation for NBCCEDP requires program to expend no less than 60% of funds for services. Reference: [42 U.S. C. § 300k (1998)]; NBCCEDP Policies & Procedures Manual (1999), Section I. B. Explanation of Screening and Diagnostic Services Worksheet: NBCCEDP Policies & Procedures Manual (1999), IV-C. C. Definition of screening and diagnostic services, NBCCEDP Policies & Procedures Manual (1999), Section II.

A-2.	Attainment of Target Level of Screening
Rationale	This indicator reflects the ability of the Program to set and reach realistic goals for service delivery. In addition, the indicator suggests the success of outreach efforts as well as a Program's success in recruiting and retaining providers to deliver services. Programs are expected to set attainable goals and to meet their target screening levels. Otherwise, budget requests should be adjusted downward to reflect realistic levels of screening. Exceeding target levels may put programs at risk for budget shortfalls.
Calculation	$\frac{\text{Number of screening services actually delivered}}{\text{Projected number of screening services proposed in requested budget}} \times 100$ Time period: Two-year average for most recent fully-completed budget years.
Data Sources	Number of screening services actually delivered: MDE reports for two fully completed budget years. Projected number of screening services proposed in requested budget: Final Screening and Diagnostic Services Worksheet for corresponding period. When final award is different than requested budget amount, Programs submit a revised Screening and Diagnostic Services Worksheet with their revised work plan.
Performance Goal	Screening numbers are at least 90% and no more than 100% of target levels.
References	Budget preparation instructions are included with each Request for Application. Cooperative Agreement Management Guidelines are listed in NBCCEDP Policies & Procedures Manual (1999), Section II. Screening and Diagnostic Worksheet and Instructions are listed in NBCCEDP Policies & Procedures Manual (1999), Section IV.

A-3	Minimization of Unobligated or Carry-over Funds
Rationale	Budget requests should realistically reflect intended activities that can be accomplished within the budget year. Chronic presence of unobligated balances suggests possible problems in implementing program as intended. Large unobligated balances may reflect problems in planning and management systems.
Calculation	$\frac{\text{Funds expended during fiscal year}}{\text{Total Dollar Amount of CDC Award}} \times 100$
Data Sources	Funds expended during fiscal year: Financial Status Report for last required reporting period. Total Dollar Amount of CDC Award: Final CDC Notice of Grant Award for corresponding year.
Minimum Standard	Program expenditures are between 75% and 100% of CDC Award for most recently completed fiscal year. Unobligated balances show that Program spending is within this range for each of the most recent three fiscal years.
References	PHS Grants Management Policy (US DHHS Publication No. (OASH) 94-50,000 (Rev.) April 1, 1994). See Chapter 8, Page 20 - Financial Status Reports (expenditure). (NBCCEDP Policies & Procedures Manual (1999), Section V.

B. Infrastructure

B-1.	**Data Management**
Rationale	Program data management systems are essential to ensure that women receive adequate tracking and followup services. Timeliness and adequacy of clinical services are tracked through data. Data also support program planning and budgeting. Programs should strive for complete, accurate, and timely data.
Calculation	"Percent of Records with One or More Errors," Minimum Data Elements Submissions, average of most recent 24-months
Data Sources	Minimum Data Elements, Edit Summary Report, "Percent of Records with One or More Errors" report from IMS. Note: This is based on cumulative percent since data may be retrospectively corrected.
Performance Goal	Programs should have an error rate in their MDE submissions of 5% or less.
References	NBCCEDP Data Users Manual, (Version 4.1) Section IV, "Data Quality Assessment."

B-2.	**Staffing**
Rationale	As outlined in the Request for Applications, the staffing plan identifies staff positions which are essential to carry out program activities. Rapid turnover or inability to recruit staff may signal problems in systems or management. Where barriers such as hiring freezes make it unreasonable to expect that key positions can be filled, budget requests should be adjusted. When necessary, Programs should look for alternative ways to ensure that adequate staffing is in place to carry out program activities as planned. A lack of key staff may jeopardize program management, data management, and client tracking.
Calculation	$\frac{\text{Number of FTEs vacant for 6 months or more}}{\text{Number of FTEs approved}} \times 100$
Data sources	As part of continuation applications, Programs will self-report the number and duration of vacant FTEs as part of the staffing section of their annual progress reports. For 2001, this indicator will be based on the number and duration of positions vacant from the period of April 1, 2000 through March 31, 2001. A two-year average will be used in subsequent years. FTEs include staff positions and positions for contractors or others who are hired or engaged to perform state-level work.
Minimum Standard	Not less than 80% nor more than 100% of state-level staff and contract positions are filled.
References	For an explanation of budget preparation and guidelines for adding or deleting personnel positions, see CDC Request for Applications for current year. Also see NBCCEDP Policies & Procedures Manual (1999) II, Appendix A: Budget Preparation, Attachment A: Sample Justification - New Personnel.

C. Service Delivery

C-1.	**Tracking abnormal test results - Breast Cancer Screening**
Rationale	Early detection of cancer requires not only that women are screened, but that cancer screening test results be interpreted in a timely manner. Tracking systems are used to ensure that all screening test results are received from providers, and that women obtain diagnostic services as needed. NBCCEDP is committed to aggressively tracking women to ensure that all women with abnormal test results receive appropriate notification and needed diagnostic services.
Calculation	Percent of records of women screened for breast cancer with an abnormal screening result or diagnostic workup planned that have a diagnostic procedure and final diagnosis recorded in the Program's MDE data submitted to CDC.
Data source	Minimum Data Elements, Data Quality Indicator Guide Version 4.1, Item #20(a). Average of most recent 24 month period.
Minimum Standard	Percent incomplete should be no more than 10% of records.
References	NBCCEDP Data Users Manual (Version 4.1), Section IV, Data Quality Assessment.

C-2.	**Tracking abnormal test results - Cervical Cancer Screening**
Rationale	Early detection of cancer requires not only that women are screened, but that cancer screening test results be interpreted in a timely manner. Tracking systems are used to ensure that all screening test results are received from providers, and that women obtain diagnostic services as needed. NBCCEDP is committed to aggressively tracking women to ensure that all women with abnormal test results receive appropriate notification and needed diagnostic services.
Calculation	Percent of records of women screened for cervical cancer with an abnormal screening result that have a diagnostic procedure and final diagnosis recorded in the Program's MDE data set submitted to CDC.
Data source	Minimum Data Elements, Data Quality Indicator Guide Version 4.1, Item #11(a). Average of most recent 24 month period.
Minimum Standard	Percent incomplete should be no more than 10% of records.
References	NBCCEDP Data Users Manual (Version 4.1), Section IV, Data Quality Assessment.

C-3.	**Ensuring timeliness of diagnosis - Breast Cancer Screening**
Rationale	Early detection of cancer requires that women with abnormal test results receive appropriate diagnostic services. CDC policies provide guidance for timeliness and adequacy of diagnosis services for abnormal breast cancer screening tests. As a condition of funding, Programs agree to provide not only screening services, but diagnostic services that meet or exceed the CDC guidance. This indicator measures one aspect of meeting the minimum standards.
Calculation	Percent of women screened for breast cancer with the time from abnormal screening test result to final diagnosis longer than 60 days
Data source	Minimum Data Elements, Data Quality Indicator Guide Version 4.1, Item #25(d). Average of most recent 24 month period.
Minimum Standard	Median time from abnormal screening test result to diagnosis is 60 days or less. Percent of women with the time from abnormal screening test result to diagnosis longer than 60 days is no more than 25% of records.
References	NBCCEDP Policies and Procedures Manual (1999), IV. NBCCEDP Data Users Manual (Version 4.1), Section IV, Data Quality Assessment.

C-4.	**Ensuring timeliness of diagnosis - Cervical Cancer Screening**
Rationale	Early detection of cancer requires that women with abnormal test results receive appropriate diagnostic services. CDC policies provide guidance for timeliness and adequacy of diagnosis services for abnormal cervical cancer screening tests. As a condition of funding, Programs agree to provide not only screening services, but diagnostic services that meet or exceed the CDC guidance. This indicator measures one aspect of meeting the minimum standards.
Calculation	Percent of women screened for cervical cancer with the time from abnormal screening test result to final diagnosis longer than 60 days
Data source	Minimum Data Elements, Data Quality Indicator Guide Version 4.1, Item # 16(d). Average of most recent 24 month period.
Minimum Standard	Median time from abnormal screening test result to diagnosis is 60 days or less. Percent of women with the time from abnormal screening test result to diagnosis longer than 60 days is no more than 25% of records.
References	NBCCEDP Policies and Procedures Manual (1999),Section IV. NBCCEDP Data Users Manual (Version 4.1), Section IV, Data Quality Assessment.

C-5.	**Ensuring timeliness of treatment - Breast Cancer**
Rationale	The effectiveness of cancer early detection rests on the assumption that early detection will result in early cancer treatment, thereby reducing morbidity and mortality. As a condition of funding, Programs agree to provide not only screening and diagnostic services, but also to ensure that women diagnosed with cancer receive appropriate treatment. CDC policies provide a minimum standard for timeliness of treatment services for women diagnosed with breast cancer. NBCCEDP takes an aggressive stance in requiring Programs to ensure that women in need of treatment services obtain actual services–not just a referral to a possible treatment source. This indicator measures one aspect of meeting the minimum standards.
Calculation	Percent of women with the time from a diagnosis of breast cancer to initiation of treatment 60 days or longer For this calculation, breast cancer is defined as in-situ breast cancer or invasive breast cancer.
Data source	Minimum Data Elements, Data Quality Indicator Guide Version 4.1, Item #27(d). Average of most recent 24 month period.
Minimum Standard	Percent of women with the time from cancer diagnosis to initiation of treatment longer than 60 days is no more than 20% of records.
References	NBCCEDP Policies and Procedures Manual (1999), Section IV. NBCCEDP Data Users Manual (Version 4.1), Section IV, Data Quality Assessment.

C-6.	**Ensuring timeliness of treatment - Cervical Cancer**
Rationale	The effectiveness of cancer early detection rests on the assumption that early detection will result in early cancer treatment, thereby minimizing cancer morbidity and mortality. As a condition of funding, Programs agree to provide not only screening and diagnostic services, but also to ensure that women diagnosed with cancer receive appropriate treatment. CDC policies provide a minimum standard for timeliness of treatment services for women diagnosed with cervical cancer. NBCCEDP takes an aggressive stance in requiring Programs to ensure that women in need of treatment services obtain actual services–not just a referral to a possible treatment source. This indicators measures one aspect of meeting the minimum standards.
Calculation	Percent of women with the time from a diagnosis of cervical cancer to initiation of treatment 60 days or longer For this calculation, cervical cancer is defined as CIN II, CIN III/CIS, or invasive cervical carcinoma.
Data source	Minimum Data Elements, Data Quality Indicator Guide Version 4.1, Item #18(d). Average of most recent 24 month period.
Minimum Standard	Percent of women with the time from cancer diagnosis to initiation of treatment longer than 60 days is no more than 20% of records.
References	NBCCEDP Policies and Procedures Manual (1999), Section IV. NBCCEDP Data Users Manual (Version 4.1), Section IV, Data Quality Assessment.

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Reimbursement Policies for Screening and Diagnostic Services

A. Screening Services: Breast Health Component

Background

When the NBCCEDP began in 1991, the CDC used the current recommendations for breast cancer screening that placed emphasis upon the value of screening mammography for women in both the 40-49 years age group and women aged 50 and older. Thus, CDC funded programs were allowed to make individual decisions about the proportion of breast cancer screenings that would be provided to eligible women in these two age groups.

CDC initiated a review of its program guidelines for mammography screening in October 1993 with input from programs participating in the NBCCEDP. Program data revealed that more than 50 percent of the screenings for breast cancer during the first year of the NBCCEDP had been provided to women less than 50 years of age. Based upon the two important facts outlined below, CDC decided that a shift in focus for the breast cancer screening component of the Program was necessary.

- Clinical trials had clearly demonstrated the efficacy of screening women aged 50-69 years, with mortality reductions of approximately 30% among this age group. However, no clinical trials contained enough women over the age of 70 to produce evidence clearly supporting the efficacy of screening in this age group. The scientific support for screening women age 40-49 years was not as clear, and both national and international debate on this issue was underway in 1993.

- CDC cost estimates for the NBCCEDP program to reach approximately 80% of the eligible population were in the $800 million range. Appropriations have been clearly inadequate to meet the needs of all eligible women.

NBCCEDP Mammography Screening Data

CDC routinely monitors the NBCCEDP screening data to determine progress in reaching older women. A significant shift in the age distribution of mammograms provided through the Program has occurred since the targets were established. However, while some programs individually met the 75% target established for FY 1995, the aggregate national mammography screening numbers have yet to reach this goal.

Rationale for Screening Services

Difficult public health decisions need to be made given the current scientific information and practical considerations, such as coverage for mammography screening among women who are low income, impact on service delivery, and the resources available for government supported screening programs. The mammography screening policy for the NBCCEDP resulted from careful review of scientific research, analysis of many complex program issues, and input from several partners.

The value of any screening test used in an asymptomatic population is dependent upon the incidence and mortality associated with the disease as well as the performance characteristics and shortcomings of the screening procedure. Clinical trials have consistently shown a significant mortality reduction benefit (30%) for women aged 50-69 years. In addition, women 50 years of age and older have higher incidence rates of breast cancer than women under 50 years of age. CDC agrees that there is a high degree of scientific confidence about the benefit of mammography for women 50-69 years of age, and that routine mammography use among women in this age group needs to be improved.

Policy for Medicare-Part B Unenrolled Women 50 Years of Age and Older

A minimum of ***75%*** percent of all NBCCEDP mammograms should be provided to program-eligible women who are Medicare-Part B **unenrolled*** women 50 years of age and older. (See Attachment A for the formula to calculate this percentage.)

* Women who are low income (250% poverty or less) and cannot pay the premium to enroll in Medicare-Part B are eligible to receive mammograms through the NBCCEDP. Mammograms provided to these women will be counted in the 75% percent.

* Women who are not eligible to receive Medicare-Part A and B are eligible to receive mammograms through the NBCCEDP. Mammograms provided to these women will be counted in the 75% percent.

* If a woman is eligible to receive Medicare benefits, but is not enrolled, she should be encouraged to enroll.

Policy for Women Under 50 Years of Age

Mammograms provided to program-eligible women under 50 years of age should not exceed a maximum of ***25%*** of all mammograms provided by the NBCCEDP.** See Attachment A for the

formula to calculate this percentage.

Symptomatic women under the age of 40 — NBCCEDP funds can be used to reimburse for clinical breast exams (CBE) for women under the age of 40. If the findings of the CBE are considered to be abnormal, including a discrete mass, nipple discharge, and skin or nipple changes, a woman can be provided a diagnostic mammogram by the program and/or referred for a surgical consult. (Refer to the Evaluation of Common Breast Problems: A Primer for Primary Care Providers for further guidance.)

Asymptomatic women under the age of 40 at increased risk for breast cancer — NBCCEDP funds cannot be used to screen asymptomatic women under the age of 40, even if they are considered to be at high risk (e.g., women who have a personal history of breast cancer or first degree relative with pre-menopausal breast cancer) for breast cancer.

** Mammograms provided prior to October 1, 1994 to women aged 40-49 at the time of the screening will not be included in this calculation. Subsequent mammograms (i.e., rescreening mammogram or short-term follow-up mammogram) provided to these same women, will only be included in the calculation if the women were 50 years of age or older at the time of the subsequent screening.

Clinical Breast Exam -
NBCCEDP funds may be used to reimburse for clinical breast exams for women under the age of 40. The NBCCEDP recommends that all women ages 18-64 years old receive an annual clinical breast exam regardless of symptoms.

Policy for Medicare-Part B Enrolled Women

Women enrolled in Medicare-Part B are not eligible for the NBCCEDP clinical services. They should be referred for appropriate screening or rescreening procedures to providers that accept Medicare reimbursement. The NBCCEDP will not continue to reimburse for additional screening services (Pap tests, pelvic exams, clinical breast exams) nor assist with co-payments associated with these services for Medicare-Part B enrolled women.

Policy for Males

Based on Public Law 101-354, men are not eligible to receive NBCCEDP screening and/or diagnostic services.

Effective Date

The Policy is effective January 1, 1998 (Federal Fiscal Year 1998). This document supersedes the document entitled, “Official Program Guidelines Age Eligibility for Mammography Screening,” October 1, 1994.

B. Screening Services: Cervical Health Component

Background

According to the American Cancer Society (ACS), an estimated 12,800 new cases of invasive cervical cancer will be diagnosed in 2000. However, the incidence of the disease has decreased significantly over the last 40 years, in large part because of early detection efforts via the Papanicolaou (Pap) test. Still, an estimated 4,600 women will die of the disease this year (1).

The primary purpose of cervical cancer screening is to identify and treat precancerous cervical lesions and detect and treat cervical cancer at an early stage. Detection and treatment of precancerous cervical lesions identified by a Pap test can prevent cervical cancer. When cervical cancer is detected while in an early stage, the likelihood of survival is almost 100% with timely and appropriate diagnostic follow-up and treatment.

Findings based upon a 1998 study of "Cervical Cancer Screening Among Low-Income Women: Results of the National Screening Program, 1991-1995" published in Obstetrics and Gynecology, conclude that, "Observed results emphasize the duality of cervical intraepithelial neoplasia--(CIN) in younger women and invasive cancer in older women. This finding emphasizes the importance of reaching both younger and older women for cervical screening." The article also states that, "Maintaining the focus on comprehensive screening programs that increase access to Papanicolaou smear testing for women of all ages must continue to be a public health priority at the federal, state and local levels" (2).

In 1999, CDC conducted a careful review of the scientific literature, professional organization guidelines related to cervical cancer and NBCCEDP data of Pap screening outcomes. In consultation with an external work group comprised of clinical experts, epidemiologists, NBCCEDP program directors, researchers, and public health practitioners and additional input from CDC staff, the following policy was developed.

This policy is not intended to be a set of clinical guidelines for the general U. S. Population. Rather, it provides programmatic and reimbursement guidance to all NBCCEDP-funded programs. The key issues addressed by this policy include:

II Increasing screening for NBCCEDP-eligible women never or rarely screened;

- **Decreasing over-screening among NBCCEDP-enrolled women;**

- **Appropriate follow-up for abnormal Pap test results and reimbursement of diagnostic procedures; and**
- **Reimbursement for new Pap testing technologies and Human Papillomavirus (HPV) testing.**

Increasing Screening for NBCCEDP Eligible Women Never or Rarely Screened.

Background and Policy Related to Program Eligible Women Never or Rarely Screened.
Fiscal year 2000 Congressional appropriations will allow the NBCCEDP to reach approximately 12-15 percent of uninsured women nationally. Given these limited resources and the impact of morbidity and mortality related to cervical cancer, CDC will prioritize screening services to never and rarely screened women who are at greatest risk for cervical cancer. Based on findings by health economists, that health benefits increase with the number of women screened, it is reasonable to conclude that conventional Pap testing of increased numbers of women will produce a greater health benefit. Therefore, NBCCEDP resources need to be re-directed toward identifying and screening never and rarely screened women. Throughout this policy, "never and rarely screened women" are defined as women who have never had a Pap test, or who have not had a Pap test within five years.

Programs will be required to demonstrate progress in meeting CDC targets for increasing cervical cancer screening to NBCCEDP-eligible women never or rarely screened.

> **Effective Date** The policy statements related to, "Increasing Screening for NBCCEDP Eligible Women Never or Rarely Been Screened" are effective 3/1/2000.

Decreasing Over-Screening Among NBCCEDP-Enrolled Women.
Background:
There are several different recommendations from national, professional and governmental organizations regarding the frequency of use and the age at which to begin Pap testing. The US Preventive Services Task Force recommends that Pap testing begin at the onset of sexual intercourse or at age 18, and that a Pap test be performed on a woman, with an intact uterus, at least every three years. The Task Force notes that intervals for each patient should be determined by the physician, based on the woman's history of risk factors (3). In 1997, the American College of Obstetricians and Gynecologists' (ACOG) Committee on Gynecologic Practice stated that "all women who are or who have been sexually active or who have reached 18 years of age should undergo an annual Pap test and pelvic examination. After a woman has had three or more consecutive, satisfactory, annual cytologic examinations with normal findings, the Pap test may be performed less frequently on a low-risk woman at the discretion of her physician (4)." ACOG did not address Pap tests for women after a hysterectomy.

In a 1992 cervical cancer screening document, the World Health Organization (WHO) suggested that annual Pap tests are often unnecessary. The WHO noted that screening resources are often used on a small proportion of the population with very little benefit. The WHO states, "it is clear that it is more cost-effective to recruit a high proportion of the population and screen them infrequently, than recruit a low proportion and screen them often (5).

A recent unpublished analysis of NBCCEDP data found that age-adjusted rates of high grade squamous intraepithial lesions (HSIL) were similar for women screened 9-12, 13-24, or 25-36 months after a documented normal smear. In addition, those women screened annually when compared to those re-screened once at a three year interval had approximately twice as many low grade smears as high-grade smears. One of the study conclusions was that clinically-significant cytologic abnormalities (i.e. HSIL) are uncommon in the three years following a normal smear and the likelihood of unnecessary diagnostic evaluations and increased patient morbidity is greater, without reducing risk of cervical cancer morbidity and mortality (17).

Policies Related to Decreasing Over-Screening among NBCCEDP-enrolled women.

1. **Policy for Medicare Part B Unenrolled Women 18 - 64 Years of Age:** NBCCEDP-funds may be used to reimburse for Pap tests on an annual basis for women 18 to 64 years of age, who have an intact cervix.
2. After a woman has had three, consecutive, normal, Pap tests within a 5-year (60 months) period, documented in the program's Minimum Data Elements (MDEs), the Pap test shall be performed every 3 years.
3. Prior to obtaining these three, consecutive, Pap tests with normal or benign findings within a 5-year (60 months) period, funds may be used to reimburse for screening services on an annual basis. If a woman receives an abnormal screening result at any time, policies related to the follow-up of abnormal Pap tests and reimbursement of diagnostic procedures should be followed. Once a women has completed recommended follow up, she may again receive annual Pap tests until three, consecutive Pap screens within a 5-year (60 months) period are normal. (Clinical scenarios are provided in Appendix A and demonstrate how this policy will operate.)

   Programs should consult with their Medical Advisory Committee to determine the parameters for physician discretion once a women meets the eligibility requirement for less frequent Pap testing. Programs will be required to demonstrate progress in meeting CDC targets of decreasing over-screening among NBCCEDP-enrolled women.

Notes: - A normal Pap test result includes the Bethesda System (TBS) classification of "benign".
-An annual Pap test is defined as a Pap test performed within 10-18 months of the previous Pap test.
-NBCCEDP-funds may not be used to pay for follow-up pelvic exams in the absence of a Pap smear, colposcopy, or biopsy.

4. **Policy for Women over 64 Years of Age:** NBCCEDP-funds may not be used to reimburse for Pap tests when a woman reaches 65 years of age and is enrolled in Medicare Part B. If a woman is eligible to receive Medicare benefits, but is not enrolled, she should be encouraged to enroll. Although the number of women 65 years of age or older and not enrolled in or eligible for Medicare Part B is minimal, the NBCCEDP may continue to reimburse for screening services for these women using the same screening interval standards established for women ages 18-64.

5. **Pap Testing Following Hysterectomy:** Approximately 35 percent of U.S. women 50 years of age or older have had a hysterectomy. The vast majority of women who have had a hysterectomy do not have a cervix and are not at risk for developing cervical cancer. NBCCEDP-funds can not be used to pay for cervical cancer screening in women with hysterectomies, unless the hysterectomy was performed due to cervical neoplasia. NBCCEDP-funds can be used to pay for an initial examination (i.e., pelvic exam) to determine if a woman has a cervix. Refer to the policy statements about the frequency of Pap testing **once three consecutive, normal Pap tests, within a 5-year (60 months) period, are recorded in the MDEs.**

   A small percentage of women have had a "supracervical hysterectomy" and have an intact cervix. The presence of a cervix can be determined on physical exam. These women are at risk of developing cervical cancer; therefore, NBCCEDP-funds may be used to pay for Pap tests. Refer to the policy statements about the frequency of Pap testing **once three consecutive, normal Pap tests, within a 5-year (60 months) period are recorded in the MDEs.**

Administrative Requirements:

1. All NBCCEDP-funded programs should develop and submit for approval an operational plan. Programs are encouraged to consult with their Medical Advisory Committee and program providers, NBCCEDP staff, and CDC program consultants during this development process.

2. Draft copies of each program's operational plan should be shared with their program consultant prior to submitting a final copy. The operational plan should include:

   Background information, data reviews and assessments, as well as activities and strategies for planning, implementing and evaluating success in meeting the following CDC targets*:

   III. At least 20% of NBCCEDP-enrolled women meet the criteria of being never or rarely screened.

d. At least 75% of NBCCEDP-enrolled women with three consecutive, normal Pap tests, within a 5-year (60 months) period, do not receive a fourth annual Pap test, and are transitioned to a three year Pap screening interval.

* CDC targets are expected to change over time.

Specific guidance and instructions for the development and submission of the cervical cancer operational plan is provided in the attached document entitled, "Suggestions for Developing a National Breast and Cervical Cancer Early Detection Program Cervical Cancer Operational Plan"

Effective Date The policy statements related to "Pap Testing Following a Hysterectomy" were effective 11/26/1991. Policy statements related to reimbursement for an initial exam (includes pelvic exam) to determine if a women has a cervix were effective 10/1/1999.

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The policy statements related to "Decreasing Over-Screening Among NBCCEDP Enrolled Women" are effective 10/01/2001. On the effective date, program enrolled women with three consecutive, Pap tests with normal findings, within a 5-year (60 months) period documented in the MDEs, will have met the criteria for Pap testing on a three year interval.

Appropriate Follow-up for Abnormal Pap Test Results and Reimbursement of Diagnostic Procedures

Background:

It is estimated that each year approximately 2.5 million women in the United States are found to have low-grade cervical cytological abnormalities (6). In 1988, the NCI sponsored a workshop to standardize cervical and vaginal cytopathology reports by classifying the wide range of abnormalities found in Pap test results. The outcome of this workshop was a new classification system known as the Bethesda System (TBS). TBS was re-examined at a 1991 workshop, and a revised and simplified version was produced (6). However, guidelines for patient management are not included in TBS.

Previously, the NBCCEDP recommended the use of the 1994 NCI-sponsored workshop guidelines for follow-up of atypical squamous cells of undetermined significance (ASCUS), low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), and squamous cell carcinoma Pap test results (6). Similar guidelines for the follow-up of atypical glandular cells of undetermined significance (AGUS) had not been previously produced. The CDC strongly encouraged programs to consult their Medical Advisory Committees or clinical experts to develop or revise guidelines based on local provider practice. In addition, the NBCCEDP did not reimburse for Loop Electrosurgical Excisional Procedure (LEEP) and

conization, as these procedures have been considered to be treatment rather than diagnostic in nature. Recently, the American Society for Colposcopy and Cervical Pathology (ASCCP) has produced guidelines for the management of AGUS (8).

Policies related to the appropriate follow-up for abnormal Pap test results and reimbursement of diagnostic procedures:

1. **ASCUS, LSIL, HSIL, and Squamous Cell Carcinoma:** NBCCEDP funded programs should refer to the 1994 *Interim Guidelines for Management of Abnormal Cervical Cytology* (6) and the 1993 *Cervical Cytology: Evaluation and Management of Abnormalities* (7) for assistance with appropriate follow-up of ASCUS, LSIL, HSIL, and squamous cell carcinoma. Programs are encouraged to consult with their medical advisory committee to develop or revise guidelines based on state, regional, or local provider practices and nationally recognized guidelines such as those mentioned above.

2. **AGUS:** For reference on appropriate follow-up of AGUS, programs should refer to the 1997 *ASCCP Practice Guidelines: Management of Glandular Abnormalities in the Cervical Smear*, from the Journal of Lower Genital Tract Disease (8), and consult their medical advisory committee to develop or revise guidelines based on state, regional, and local provider practice and nationally recognized guidelines such as those mentioned above.

3. **Diagnostic Procedures:** NBCCEDP-funds may be used to reimburse for colposcopy, colposcopy-directed biopsy, endocervical curettage and pathology fees (see attachment B for Current Procedural Terminology, or CPT code listing).

   NBCCEDP funds may not be used to reimburse for LEEP or conization. These procedures are generally considered to be treatment and therefore, not a screening or diagnostic tool. Only rarely is LEEP or conization used in place of a colposcopic biopsy. In addition, NBCCEDP funds may not be used to reimburse for colposcopy performed as part of a LEEP procedure.

   If a program-eligible woman receives an AGUS diagnosis, the tool used for additional diagnostic follow-up should be colposcopy. NBCCEDP funds may not be used to reimburse for an endometrial biopsy as follow-up to an AGUS diagnosis.

   NBCCEDP-funds may be used to reimburse for colposcopy, or colposcopy with biopsy, for women referred into the program with documentation of the most recent abnormal Pap test result. Results of the abnormal Pap test must be documented in the program's MDEs. NBCCEDP-funds may not be used to reimburse for a repeat Pap test which is performed simultaneously with colposcopy or colposcopy with biopsy, unless more than four months have passed since the initial Pap test was performed.

Effective Date: The policy statements related to the Appropriate Follow-up for Abnormal Pap Test Results and Reimbursement of Diagnostic Procedures section of the Programmatic and Reimbursement Policies for Screening and Diagnostic Services: Cervical Health Component are effective 10/01/1999.

New Technologies

Background:

New cytotechnologies include automated interpretation of Pap tests and liquid-based slide preparations. Automated screening technologies, such as AutoPap® and PAPNET®, use a computer to read Pap slides. Liquid-based preparations, such as ThinPrep®, use a liquid preservative to store the sample of cervical cells. Slides are created by putting down a thin, even layer of the liquid containing the cells and are subsequently read by a cytotechnologist or pathologist.

The literature suggests that the new technologies appear more sensitive, but not more specific, than conventional Pap tests. Preliminary results demonstrate several quality improvements, including increased sensitivity (the likelihood of identifying women with cervical neoplasia) and decreased spurious ASCUS and AGUS (9). An article in the Journal of the American Medical Association (JAMA) reported that "the new technologies increased life expectancy by five hours to 1.6 days, varying with the technology and the frequency of screening. All three technologies, (AutoPap®, PapNet® and ThinPrep®), also increased the cost per woman screened by $30 to $257 [1996 U.S. dollars] (10)."

An evaluation of cervical cytology, released in January 1999, by the Agency for Health Care Policy and Research, determined that the cost-effectiveness of liquid-based preparations and automated screening technology is directly related to the frequency of screening. They noted that longer screening intervals result in lower estimates of cost per life year saved. The study also pointed out that "[a]lthough it is clear that both thin-layer cytology and computerized rescreening technologies provide an improvement in effectiveness at higher cost, the imprecision in effectiveness makes drawing conclusions about the relative cost-effectiveness of thin-layer cytology and computerized rescreening technologies problematic (11)."

In spite of the increased sensitivity of new technologies, the American College of Obstetricians and Gynecologists stated in August 1998, that the routine use of the new Pap test technologies "[could] not be recommended based on costs and the lack of sufficient data demonstrating whether they reduce the incidence of, or improve the survival rate from, invasive cervical cancer (12)."

The cost of the new technologies may affect access to care. According to Dr. Alan Garber the

author of the previously cited JAMA study, the added expense of the new testing methods may limit access to Pap testing since the majority of cervical cancer cases and mortality are concentrated among underserved populations, especially women who have not been screened.

The authors of the JAMA article further commented that "the major barrier to prevention of cervical cancer is not the accuracy of the Pap test, but the failure to be screened at all…If their high cost deters participation in cervical cancer screening programs, [these technologies] will not reduce the toll of the disease (10)."

Policies related to the Reimbursement of New Technologies:

1. **Liquid-Based Technologies and Automated Technologies Approved for Primary Screening of Pap Tests:** CDC understands that reimbursement of liquid-based and automated technologies for primary screening may be critical to the operation of some programs and without the flexibility to reimburse for these technologies access to care may be hindered. Due to the cost of these technologies, higher reimbursement rates would reduce the number of women screened through the NBCCEDP and increase the overall cost of cervical cancer screening. Currently, CDC does not endorse the use of these new technologies. Therefore, NBCCEDP-funds may not be used to reimburse for liquid-based technologies and automated technologies approved by FDA for primary screening unless the reimbursement rate for the new technology does not exceed the current reimbursement rate for a conventional Pap Test. No exceptions related to the reimbursement rate for the new technology will be considered.

   The NBCCEDP will re-examine this policy when further effectiveness data are available surrounding the use of liquid-based technologies and automated technologies approved for primary screening. FDA-approved examples of these technologies include ThinPrep® (liquid-based technology) and AutoPap® (automated technology approved for primary screening).

2. **Automated Screening Technologies Approved for Quality Assurance:** NBCCEDP-funds may not be used to reimburse for the automated technologies when used as a secondary assessment of Pap testing for quality assurance purposes. These quality assurance costs are built in to the pricing of tests and are paid by the cytopathology laboratories. FDA-approved examples of these automated technologies include PAPNET® and AutoPap®.

Effective Date: The policy statements related to the Reimbursement of New Technologies section of the Programmatic and Reimbursement Policies for Screening and Diagnostic Services: Cervical Health Component are effective 10/01/1999.

Human Papillomavirus (HPV)

Background:

Infection with the Human Papillomavirus (HPV) is a major risk factor for invasive cervical cancer (13). Given this relationship between HPV and cervical cancer, HPV/DNA testing may be an useful addition to conventional Pap testing. According to a recent article in *Acta Cytolgica*, simultaneous HPV and Pap testing will detect greater than 95% of high-grade lesions and invasive cancers (14). The article also states that women who are repeatedly HPV/DNA and smear negative, or "double negative," benefit from a substantially reduced risk of developing an abnormal smear compared to the general population. The authors believe that the screening interval for these women could be lengthened without fear of missing a clinically significant lesion.

HPV/DNA testing may also be used to determine the appropriate follow-up of ASCUS and LSIL Pap test results. A number of authors have reported that HPV/DNA positivity is a highly sensitive method of detecting true cervical intraepithelial neoplasia (CIN) (14). The test would help distinguish "false positive" and "true positive" Pap test results, allowing for more appropriate decisions regarding colposcopy, biopsy and treatment. Currently, a large clinical trial using the HPV test in conjunction with a liquid-based Pap test preparation is being conducted through the National Cancer Institute (NCI) to determine the utility and cost-effectiveness of HPV testing for the management of ASCUS and LSIL. Subsequently, the LSIL portion of the study was terminated because analysis of data showed that a high percentage of women with LSIL had positive HPV/ DNA so there was limited potential for the assay to direct decisions about the clinical management of women with LSIL (18). In addition, a recent observational study conducted in Northern California found that, “for women with ASCUS Pap tests, HPV/DNA testing of residual specimens collected for routine cervical cytology can help identify those who have underlying HSIL (15).” This study was designed on a large scale with 995 cohort study participants belonging to the Kaiser Permanente Medical Care Program, Northern California Region. To date, the study has not been replicated.

Critics of HPV testing note that there is no treatment for the infection once it is detected (16). In addition, HPV testing is questionable. This is especially true for women under 30 years of age. The British Journal of Cancer states that HPV screening in this age group would result in unnecessary follow-up of infections that would spontaneously resolve (13).

Before effective public health strategies to detect and prevent HPV infection can be implemented, critical gaps in our current knowledge about the usefulness of HPV testing for cervical cancer screening should be addressed. Studies are underway to determine if using HPV/DNA tests, along with the Pap test, will increase the test specificity. In addition, as mentioned previously, the utility and cost-effectiveness of HPV testing for the management of ASCUS and LSIL are being explored in ongoing studies.

***Policy Related to Reimbursement of HPV Testing*:**

1. Until further research results are available, NBCCEDP-funds may not be used to reimburse for HPV/DNA tests. The NBCCEDP will re-examine this policy when further effectiveness data are available surrounding the use of HPV/DNA testing.

Effective Date: The policy statement related to the Human Papillomavirus (HPV) section of the Programmatic and Reimbursement Policies for Screening and Diagnostic Services: Cervical Health Component is effective 10/01/1999.

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C. Breast and Cervical Diagnostic Services

Background

A system for providing appropriate diagnostic and treatment services for women with abnormal screening test results is an essential component of any breast and cervical cancer early detection program. The NBCCEDP has paid for select diagnostic procedures including diagnostic mammography, breast ultrasound, fine needle aspiration, colposcopy, and colposcopy with biopsy. The goal of this policy is to increase a program's flexibility by expanding the list of reimbursable procedures to assist with meeting the diagnostic needs of women screened through the NBCCEDP, **while assuring that the Program remains consistent with the intent of Public Law 101-354.** Priority for diagnostic services should be given to women screened in the NBCCEDP who have abnormal screening results, as opposed to those women screened in other programs and referred to the NBCCEDP for diagnostic services.

Reimbursement Policy for Diagnostic Services

Many women with an abnormal screening test result will not need all of the diagnostic procedures listed in Attachment B. To guide the appropriate use of these procedures, clinical guidelines should be established in each program in consultation with the program's Medical Advisory Committee and/or clinical experts in breast and cervical cancer diagnosis. It is recommended that each program's clinical guidelines build upon "Evaluation of Common Breast Problems: Guidance for Primary Care Providers," CA-A Cancer Journal For Clinicians, Vol 48, No 1 January/February 1998, the "Cervical Cytology Evaluation and Management of Abnormalities," American College of Obstetricians and Gynecologists (ACOG) Technical Bulletin (Number 183-August 1993), and the "Interim Guidelines for the Management of Abnormal Cervical Cytology," (JAMA 1994; 271:1866-9).

Programs are also responsible for monitoring their providers for potential over utilization of screening and diagnostic services. Payment for the diagnostic procedures must not exceed the maximum State/territorial Medicare reimbursement rate for this procedure. In addition, diagnostic procedures reimbursed through the NBCCEDP must only be reimbursed on an outpatient basis.

While programs are required in their grant application to list all of the usual procedures and estimate their overall costs, in unique situations, programs may desire to occasionally provide a service that they had not initially anticipated. Programs have the authority to do this and need to be guided by 1) the intent of the law, 2) the list of allowable CPT codes and dissallowed CPT codes, and 3) prudent expenditures of funds. If programs want to use this discretionary option,

they must provide an explanation of their process for deciding such exceptions in their grant application.

Approval Process

In all continuation and competitive applications, the proposal must include:

a. A Screening and Diagnostic Worksheet (see Instructions on Attachment C and accompanying Worksheets) that projects on an annual basis the number of women to be screened by the program, the estimated number of abnormal screening results, and the estimated diagnostic services costs.

b. A description of:

- The guidelines upon which a Program's clinical guidance has been developed or reviewed.
- The staff who will be responsible for the oversight of diagnostic services;
- The process to monitor the use and reimbursement of diagnostic services; and
- A system for the timely and appropriate referral, tracking, and follow-up of women with abnormal screening results.
- The process by which any exceptions to a stated policies and procedures are made.

Attachment A: Formula for Calculating the Percentage of Mammograms Provided

1. Only NBCCEDP-funded mammograms (Mammogram Paid = Yes) will be included in this calculation.

2. Mammograms that are reported in the mammogram field of the All Patients Section of the Minimum Data Elements will be included in this calculation. This mammogram field represents the first mammogram of a screening cycle.

3. Only mammograms with a valid test result of Negative, Benign Finding, Probably Benign, Suspicious Abnormality, Highly Suggestive of Malignancy, Assessment is Incomplete, and Unsatisfactory will be included in the calculation.

4. Calculating Percentage for ≥50 Years of Age

   Numerator: Number including All NBCCEDP funded mammograms with a valid result provided to women 50 years of age and older.
   Denominator: Number including All NBCCEDP funded mammograms with a valid result provided to women of all ages.
   Grandmother Clause: Mammograms provided prior to October 1, 1994 to women aged 40-49 at the time of the screening will not be included in this calculation. Subsequent mammograms (i.e., rescreening mammogram or short-term follow-up mammogram) provided to these same women, will only be included in the calculation if the women were 50 years of age or older at the time of the subsequent screening.

5. Calculating Percentage for <50 Years of Age

   Numerator: Number including All NBCCEDP funded mammograms with a valid result provided to women less than 50 years of age.
   Denominator: Number including All NBCCEDP funded mammograms with a valid result provided to women of all ages.
   Grandmother Clause: Mammograms provided prior to October 1, 1994 to women aged 40-49 at the time of the screening will not be included in this calculation. Subsequent mammograms (i.e., rescreening mammogram or short-term follow-up mammogram) provided to these same women will only be included in the calculation if the women were 50 years of age and older at the time of the subsequent screening.

Attachment B: NBCCEDP 2001 CPT Codes

Listed below is the suggested list of 2001 CPT codes for the NBCCEDP. Programs may request to utilize or substitute similar codes by contacting their program consultant and justifying the requests in their continuation or cooperative agreement application.

BREAST	
Screening	
Screening mammogram	76092
Diagnostics	
Diagnostic/Follow-up — Unilateral Mammogram	76090
Diagnostic/Follow-up — Bilateral Mammogram	76091
Stereotactic localization for breast biopsy, each lesion, radiological supervision, and interpretation	76095
Preoperative placement of needle localization wire, breast, radiological supervision, and interpretation	76096
Radiological examination, surgical specimen	76098
Ultrasound — Echography, Breasts (unilateral or bilateral) B-scan and/or real time with image documentation	76645
Ultrasonic guidance for cyst aspiration, radiological supervision, and interpretation	76938
Ultrasonic guidance for needle biopsy, radiological supervision, and interpretation	76942
Aspiration of Cyst of Breast	19000
Aspiration of Cyst of Breast, Additional	19001
Biopsy of breast; needle core (surgical procedure only)	19100
Incisional biopsy of breast	19101
****Percutaneous, needle core, using imaging guidance**	**19102**

****Percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance**	**19103**
Excision of cyst, fibroadenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion, or nipple lesion	19120
Excision of breast lesion identified by pre-operative placement of radiological marker - single lesion	19125
Excision of breast lesion identified by pre-operative placement of radiological marker - each additional lesion	19126
Preoperative placement of needle localization wire, breast	19290
**** Image guided placement metallic localization clip, percutaneous, during breast biopsy**	**19295**
Fine Needle Aspiration with/without preparation of smears	88170
Evaluation of Fine Needle Aspiration	88172
Interpretation and Report of Fine Needle Aspiration	88173
Breast biopsy interpretation	88305
CERVICAL	
Screening	
Pap Smear, reported in Bethesda System	88164
Pap Smear, reported in Bethesda System requiring interpretation by physician	88141
Diagnostic	
Colposcopy Biopsy Interpretation	88305
Colposcopy without Biopsy (surgical procedure only)	57452
Colposcopy with Biopsy and/or endocervical curettage (surgical procedure only)	57454
OFFICE VISITS	
New Patient — Office Visit (10 minutes face to face)	99201
New Patient — Office Visit (20 minutes face to face)	99202

New Patient — Office Visit (30 minutes face to face)	99203
Established Patient — Office Visit (5 minutes face to face)	99211
Established Patient — Office Visit (10 minutes face to face)	99212
Established Patient — Office Visit (15 minutes face to face)	99213
Consultation Visit — 15 minutes face-to-face with patient	99241
Consultation Visit — 30 minutes face-to-face with patient	99242
Consultation Visit — 40 minutes face-to-face with patient	99243
Initial Preventive Medicine Evaluation – 18-39 years	**99385**
Initial Preventive Medicine Evaluation — 40-64 years	99386
Initial Preventive Medicine Evaluation — 65 years and older *	99387*
Periodic preventive Medicine Evaluation – 18-39 years	**99395**
Periodic Preventive Medicine Evaluation — 40-64 years	99396
Periodic Preventive Medicine Evaluation — 65 years and older*	99397*

Other fees associated with the above procedures may be reimbursable on an outpatient basis, e.g. facility fees, general/regional anesthesia.

* Reimbursable for Medicare-Part B unenrolled women only.
** New 2001 codes
All codes added to this list for 2001 are **bolded.**

Listed below are procedures that have been determined to not be allowable:

LEEP (Loop Electrode Excision Procedure)
Cone Biopsy
Endometrial Biopsy
Any Treatment of breast cancer, cervical intraepithelial neoplasia and cervical cancer

	A	B	C	D	E	F	G	H
1								
2	SCREENING AND DIAGNOSTIC WORK-UP CALCULATIONS SHEET							
3								
4	CALCULATIONS INPUT							
5								
6	NUMBER OF WOMEN SCREENED						**Program X**	Cost of each procedure
7	New Screens: mammograms			3,000				
8	Subsequent mammograms			1,000				
9	Total mammograms			4,000				$ 63.76
10								
11	Number of screening CBE's			4,000				
12								
13	New Screens: PAPs			3,000				
14	Subsequent PAPs			1,000				
15	Total PAPs			4,000				$ 14.60
16								
17	New office visits			3,000			New Pt	$ 45.86
18	Subsequent office visits			1,000			Established pt	$ 25.33
19	Total office visits			4,000				
20								
21	ASSUMPTIONS REGARDING RATES OF ABNORMALS AND PROCEDURES (percentages modified 10/2000)							
22	Rate of abnormal mammograms new (5-10%)				9.1%			
23	Rate of abnormal mammograms - subsequent				5.3%			
24	Rate of abnormal CBE's (with normal mammogram)				4.4%			
25	Rate of ASCUS Paps				4.8%			
26	Rate of LSIL Paps				1.7%			
27	Rate of HGSIL and SqCa Paps				0.6%			
28	Rate of each procedure following an abnormal mammogram							Cost of each procedure
29		Diagnostic Mam (addt'l mam views)			53.4%			$ 60.00
30		Ultrasound			39.7%			$ 67.93
31		FNA			7.1%			$ 63.38
32		Biopsy(non excisional)			7.8%			$ 80.00
33		Excisional biopsy			15.5%			$ 350.00
34		Surgical consult			31.5%			$ 67.18
35					Pathology charges: breast			$ 69.96
36								
37	Rate of each procedure following an abnormal CBE (with normal mam)							
38		Diagnostic Mam (addt'l mam views)			14.0%			
39		Ultrasound			50.0%			
40		FNA			8.0%			
41		Biopsy (non exc.)			3.1%			
42		Excisional biopsy			6.3%			
43		Surgical Consult			93.0%			

	A	B	C	D	E	F	G	H
44	Rate of each procedure following ASCUS Pap smear							
45		Colpo-directed Biopsy			69.9%			$ 85.05
46		Colposcopy alone			5.0%			$ 56.38
47		Repeat Pap smears			100.0%			$ 15.96
48					Pathology charges: cervical			$ 64.90
49	Rate of each procedure following LSIL Pap smear							
50		Colpo-directed Biopsy			78.0%			$ 85.05
51		Colposcopy alone			11.7%			$ 56.38
52		Repeat Pap smears			100.0%			$ 15.96
53					Pathology charges: cervical			$ 64.90
54	Rate of each procedure following HGSIL and SqCa Pap smear							
55		Colpo-directed Biopsy			78.6%			$ 85.05
56		Colposcopy alone			6.4%			$ 56.38
57		Repeat Pap smears			100.0%			$ 15.96
58					Pathology charges: cervical			$ 64.90
59	CALCULATIONS USING ABOVE RATES							
60								
61	Total abnormal mams			326				
62	Total abnormal CBE's (normal Mam)			176				
63	Total ASCUS Paps			192				
64	Total LSIL Paps			68				
65	Total HGSIL and SqCa Paps			24				
66								
67	TOTAL NUMBERS AND COSTS OF SCREENING AND DIAGNOSTIC PROCEDURES							
68		Mammogram			4,000		$ 255,040	43.0%
69		Pap smears			4,000		$ 58,400	9.8%
70		Office visits			4,000		$ 162,910	27.5%
71		Colposcopy/biopsy			206		$ 17,530	3.0%
72		Colposcopy alone			19		$ 1,076	0.2%
73		Diagnostic Mam (addt'l mam views)			199		$ 11,923	2.0%
74		Ultrasound			217		$ 14,769	2.5%
75		FNA			37		$ 2,359	0.4%
76		Biopsy(non excisional)			31		$ 2,471	0.4%
77		Excisional biopsy			62		$ 21,566	3.6%
78		Repeat pap smear			284		$ 4,533	0.8%
79		Surgical consult			266		$ 17,895	3.0%
80		Pathology; breast			130		$ 9,076	1.5%
81		Pathology cervical			206		$ 13,377	2.3%
82		TOTALS			13,657		$ 592,925	100.0%

	A	B	C	D	E	F	G	H
1								
2	SCREENING AND DIAGNOSTIC WORK-UP CALCULATIONS SHEET							
3				(Key Formulas)				
4	CALCULATIONS INPUT							
5								
6	NUMBER OF WOMEN SCREENED						**Program X**	Cost of each procedure
7	New Screens: mammograms			3,000				
8	Subsequent mammograms			1,000				
9	Total mammograms			SUM(D7:D8)				$ 63.76
10								
11	Number of screening CBE's			4,000				
12								
13	New Screens: PAPs			3,000				
14	Subsequent PAPs			1,000				
15	Total PAPs			SUM(D13:D14)				$ 14.60
16								
17	New office visits			3,000			New Pt	$ 45.86
18	Subsequent office visits			1,000			Established pt	$ 25.33
19	Total office visits			SUM(D17:D18)				
20								
21	ASSUMPTIONS REGARDING RATES OF ABNORMALS AND PROCEDURES (percentages modified 10/2000)							
22	Rate of abnormal mammograms new (5-10%)				9.1%			
23	Rate of abnormal mammograms - subsequent				5.3%			
24	Rate of abnormal CBE's (with normal mammogram)				4.4%			
25	Rate of ASCUS Paps				4.8%			
26	Rate of LSIL Paps				1.7%			
27	Rate of HGSIL and SqCa Paps				0.6%			
28	Rate of each procedure following an abnormal mammogram							Cost of each procedure
29		Diagnostic Mam (addt'l mam views)			53.4%			$ 60.00
30		Ultrasound			39.7%			$ 67.93
31		FNA			7.1%			$ 63.38
32		Biopsy(non excisional)			7.8%			$ 80.00
33		Excisional biopsy			15.5%			$ 350.00
34		Surgical consult			31.5%			$ 67.18
35					Pathology charges: breast			$ 69.96
36								
37	Rate of each procedure following an abnormal CBE (with normal mam)							
38		Diagnostic Mam (addt'l mam views)			14.0%			
39		Ultrasound			50.0%			
40		FNA			8.0%			
41		Biopsy (non exc.)			3.1%			
42		Excisional biopsy			6.3%			
43		Surgical Consult			93.0%			

	A	B	C	D	E	F	G	H
44	Rate of each procedure following ASCUS Pap smear							
45		Colpo-directed Biopsy			69.9%			$ 85.05
46		Colposcopy alone			14.8%			$ 56.38
47		Repeat Pap smears			100.0%			$ 15.96
48					Pathology charges: cervical			$ 64.90
49	Rate of each procedure following LSIL Pap smear							
50		Colpo-directed Biopsy			78.0%			$ 85.05
51		Colposcopy alone			11.7%			$ 56.38
52		Repeat Pap smears			100.0%			$ 15.96
53					Pathology charges: cervical			$ 64.90
54	Rate of each procedure following HGSIL and SqCa Pap smear							
55		Colpo-directed Biopsy			78.6%			$ 85.05
56		Colposcopy alone			6.4%			$ 56.38
57		Repeat Pap smears			100.0%			$ 15.96
58					Pathology charges: cervical			$ 64.90
59	CALCULATIONS USING ABOVE RATES							
60								
61	Total abnormal mams			(D7*F22)+(D8*F23)				
62	Total abnormal CBE's (normal Mam)			D11*F24				
63	Total ASCUS Paps			D15*F25				
64	Total LSIL Paps			D15*F26				
65	Total HGSIL and SqCa Paps			D15*F27				
66								
67	TOTAL NUMBERS AND COSTS OF SCREENING AND DIAGNOSTIC PROCEDURES							
68		Mammogram			SUM(D7:D8)		E68*H9	G68/G82
69		Pap smears			SUM(D13:D14)		E69*H15	G69/G82
70		Office visits			SUM(D17:D18)		(D17*H17)+(D18*H18)	G70/G82
71		Colposcopy/biopsy		(D63*D45)+(D64*D50)+(D65*D55)			E71*H55	G71/G82
72		Colposcopy alone		(D63*D46)+(D64*D51)+(D65*D56)			E72*H56	G72/G82
73		Diagnostic Mam (addt'l mam views)		(D61*D29)+(D62*D38)			E73*H29	G73/G82
74		Ultrasound		(D61*D30)+(D62*D39)			E74*H30	G74/G82
75		FNA		(D61*D31)+(D62*D40)			E75*H31	G75/G82
76		Biopsy(non excisional)		(D61*D32)+(D62*D41)			E76*H32	G76/G82
77		Excisional biopsy		(D61*D33)+(D62*D42)			E77*H33	G77/G82
78		Repeat pap smear		(D63*D47)+(D64*D52)+(D65*D57)			E78*H57	G78/G82
79		Surgical consult		(D61*D34)+(D62*D43)			E79*H34	G79/G82
80		Pathology; breast		D61*(D31+D32+D33)+D62*(D40+D41+D42)			E80*H35	G80/G82
81		Pathology cervical		(D63*D45)+(D64*D50)+(D65*D55)			E81*H58	G81/G82
82		TOTALS			SUM(E68:E81)		SUM(G68:G81)	G82/G82

Attachment D: Clinical Scenarios for Screening Services: Cervical Health Component

Clinical Scenario #1:

A woman receives her first Pap smear with the NBCCEDP on October 1, 1994. The Pap smear provides a result of "Negative". The clinician recommends that patient return for another Pap smear in a year.

The woman returns on November 10, 1995 for a second Pap smear in the NBCCEDP. The Pap smear provides a result of "Infection". The clinician recommends that the patient return for another Pap smear in a year.

The woman returns on December 1, 1996 for a third Pap smear in the NBCCEDP. The Pap smear provides a result of "Negative". The clinician explains to the woman that she has now received 3 consecutive annual "Negative" Pap smears and the good news is that she does not need another Pap smear for 3 years. The clinician recommends that the patient return for another Pap smear in 3 years.

The woman returns on November 1, 1999 for a fourth Pap smear in the NBCCEDP. The Pap smear results in a "Negative" finding. The clinician recommends that the woman return for another Pap smear in 3 years.

Visual Display of Scenario #1:

Pap 1	Pap 2	Pap 3	Pap 4	Pap 5
"Neg"	"Inf"	"Neg"	"Neg"	Scheduled for
X	X	X	X	X
Oct 1994	Nov 1995	Dec 1996	Nov 1999	Nov 2002

Clinical Scenario #2:

A woman receives her first Pap smear with the NBCCEDP on August 15, 1995. The Pap smear provides a result of "Negative". The clinician recommends that patient return for another Pap smear in a year.

The woman returns on December 10, 1996 for a second Pap smear in the NBCCEDP. The Pap smear provides a result of "Infection". The clinician recommends that the patient return for another Pap smear in a year.

The woman returns on February 1, 1998 for a third Pap smear in the NBCCEDP. The Pap smear provides a result of "Low Grade SIL". The clinician recommends a colposcopy w/biopsy to evaluate the lesion. The colposcopy w/biopsy returns as "Benign". The clinician then recommends that the woman return for a Pap smear in 6 months.

The woman returns on August 15, 1998 for a fourth Pap smear in the NBCCEDP. The Pap smear results with a finding of "Negative". The clinician recommends that the patient return for another Pap smear in a year.

The woman returns on August 1, 1999 for a fifth Pap smear in the NBCCEDP. The Pap smear results with a finding of "Negative". The clinician recommends that the patient return for another Pap smear in a year.

The woman returns on September 1, 2000 for a sixth Pap smear in the NBCCEDP. The Pap smear results with a finding of "Negative". The clinician explains to the woman that she has now received 3 consecutive annual "Negative" Pap smears and the good news is that she does not need another Pap smear for 3 years. The clinician recommends that the woman return in 3 years for another Pap smear.

Visual Display of Scenario #2:

Pap 1 "Neg"	Pap 2 "Inf"	Pap 3/Biopsy "LSIL/Benign"	Pap 4 "Neg"	Pap 5 "Neg"	Pap 6 "Neg"	Pap 7 Scheduled
X	X	X	X	X	X	X
Aug 1995	Dec 1996	Feb 1998	Aug 1998	Aug 1999	Sep 2000	Sep 2003

Clinical Scenario #3:

A woman receives her first Pap smear with the NBCCEDP on August 15, 1995. The Pap smear provides a result of "Negative". The clinician recommends that patient return for another Pap smear in a year.

The woman is no longer eligible to receive screening through the NBCCEDP. However, she visits a non-NBCCEDP provider on December 10, 1996 for a second Pap smear. The Pap smear provides a result of "Infection". The non-NBCCEDP provider recommends that she return for another Pap smear in a year.

The woman has lost her job and once again meets the eligibility requirements to receive services through the NBCCEDP. She returns on February 1, 1998 for a second Pap smear in the NBCCEDP. The Pap smear provides a result of "Negative". If the clinician knows the Pap smear result from the previous year, then he informs the woman that she has had 3 consecutive annual "Negative" Pap smears and that she does not need another Pap smear for 3 years. On the other hand, if the clinician does not have the result from the non-NBCCEDP provider, then he may recommend a Pap smear in a year.

The clinician knows the result of the non-NBCCEDP Pap smear:
The woman returns on March 15, 2001 for a third Pap smear in the NBCCEDP. The Pap smear results with a finding of "Negative". The clinician recommends that the patient return for another Pap smear in 3 years.

The woman returns on March 15, 2004 for a fourth Pap smear in the NBCCEDP. The Pap smear results with a finding of "Negative". The clinician recommends that the patient return for another Pap smear in 3 years.

The clinician does NOT have the result from the non-NBCCEDP Pap smear:
The woman returns on March 30, 1999 for a third Pap smear in the NBCCEDP. The Pap smear results with a finding of "Negative". The clinician informs the woman that she has had 3 consecutive annual "Negative" Pap smears and that she does not need another Pap smear for 3 years. The clinician recommends that she return for another Pap smear in 3 years.

The woman returns on April 1, 2002 for a fourth Pap smear in the NBCCEDP. The Pap smear results with a finding of "Negative". The clinician recommends that the patient return for another Pap smear in 3 years.

Visual Display of Scenario # 3:

Pap 1	*Pap 2	Pap 3	**Pap 4	**Pap 5
"Neg"	"Inf"	"Neg"	"Neg"	"Neg"
X	X	X	X	X
Aug 1995	Dec 1996	Feb 1998	Mar 2001 or Mar 1999	Mar 2004 or Apr 2002

*Non-NBCCEDP funded Pap smear
** For Pap 4 and Pap 5, the dates that these Pap smears are performed depends on having the information about Pap 2. Since Pap 2 was done by an outside provider, the NBCCEDP may not be able to get this information and the woman may not provide it. Therefore, the NBCCEDP provider would recommend that the woman return in a year for another Pap smear. If data for Pap 2 is available, then the NBCCEDP provider would recommend that the woman return in 3 years for another Pap smear.

Policy on the Inclusion of Data in the MDEs

Goal

The overall goal of this document is to clarify the intent of the NBCCEDP MDEs and establish a policy for the inclusion of data in this surveillance system. To develop this policy, a committee was formed in the Division of Cancer Prevention and Control consisting of representatives from the Epidemiology and Statistics Branch (now EHSRB and CSB), Program Services Branch (PSB), the Office of the Director, and staff from Information Management Services (IMS), the data contractor for the NBCCEDP. The objectives of the committee were to clarify the purpose of the MDEs, operationally define program funds and blended funds, and identify data to be reported in the MDEs. The CDC obtained input about this issue through a series of consultation meetings with programs, particularly those that receive State funds to support screening and diagnostic services.

Background

The CDC is entering the tenth year of implementing the NBCCEDP. Fifty States, the District of Columbia, six U.S. territories, and twelve American Indian and Alaska Native tribes and tribal organizations are receiving funds for a comprehensive screening program. When the NBCCEDP was established in 1991, few programs had existing resources for breast and cervical cancer control. In recent years, more programs have obtained other resources, in addition to NBCCEDP funds, to expand screening, diagnostic and/or laboratory services. These programs have advocated to submit data in the MDEs on all women screened through their programs, regardless of payment source. However, the CDC maintains that the MDEs must reflect screening and/or diagnostic procedures paid for in whole or in part by NBCCEDP funds, not including clinical procedures paid in full by other resources.

The CDC recognizes that each program should design a data system that meets program needs, allows for ongoing assessment of screening efforts, and provides data to respond to requests for information. The CDC also recognizes that programs often need additional data to assess cancer control efforts at the local, State, tribal and territory level beyond what is routinely reported in the MDEs.

Purpose of MDEs

The MDEs are a set of standardized data elements developed, in collaboration with funded programs, to collect demographic and clinical information on women screened with NBCCEDP funds. These data are **minimally** necessary for the CDC to monitor the clinical services provided to women screened through the National program. The MDEs are also used to establish NBCCEDP policies and practices, assess the National program's screening outcomes, and respond to the information needs of the CDC stakeholders and partners. The MDEs are not intended to reflect a

comprehensive picture of all screening services provided at the local, State, tribal, territory, or national level. Therefore, the CDC expects that programs will design data systems that capture the additional information needed to monitor and assess screening efforts.

MDE Definitions

- ***Eligible Women*** — Defined by the NBCCEDP as low-income, uninsured and underinsured women at 250% poverty or less.

- ***Clinical Services*** — Defined as breast and cervical cancer screening and diagnostic procedures performed by providers and laboratory services. Also, includes costs associated with the office visit. See the NBCCEDP Administrative Requirements and Guidelines for the CPT codes recommended by the CDC.

- ***Program Funds*** — Defined as clinical services paid for entirely by NBCCEDP funds.

- ***Blended Funds*** — NBCCEDP funds in combination with State, private, or other Federal funds for payment of clinical services. **Note: When reporting these data in the MDEs, programs must be able to distinguish NBCCEDP funds from all other funding sources.** See Attachment E for specific examples of blended funding scenarios.

Policy

The MDEs should include screening and/or diagnostic data for eligible women in the following scenarios:

- Solely paid for by NBCCEDP funds; or
- Paid for in part by NBCCEDP funds and any other funding source (e.g., State, private or other Federal funds) with the ability to distinguish the funds contributed by the NBCCEDP.

Screening and diagnostic data collected on women reported in the MDEs must meet all data quality standards set by the CDC. Programs should not submit data on women for whom clinical services are covered solely by State, private or other Federal funds. This includes women for whom clinical services are used as a source of match. Medicare-Part B Enrolled Women should not be included in the MDEs. Please refer to Attachments E and F to determine what data to report in the MDEs.

Effective Date

This Policy is effective January 1, 1998 (Federal Fiscal Year 1998).

Attachment E: Examples of Allowable Blended Funding Scenarios

1. If a woman has a pap test paid for by any other funding source and cervical diagnostic procedures (e.g., colposcopy) were paid for by the NBCCEDP funds, then **all** cervical data should be reported in the MDEs.*

2. If a woman has a CBE (as part of an office visit) and a mammogram paid for by the NBCCEDP funds and breast diagnostic procedures (e.g., breast biopsy) were paid for by any other funding source, then **all** breast data should be reported in the MDEs.

3. If a woman has a CBE (as part of an office visit) and a mammogram paid for by any other funding source and breast diagnostic procedures (e.g., breast biopsy) were paid for by the NBCCEDP funds, then **all** breast data should be reported in the MDEs.*

4. If a woman has a CBE funded by any other funding source and the mammogram paid for by NBCCEDP funds and breast diagnostic procedures (e.g., breast biopsy) were paid for by any other funding source, then **all** breast data should be reported in the MDEs.

5. If NBCCEDP only pays for the office visit (which includes the CBE, pelvic exam, and pap test) and all other screening, diagnostic and/or laboratory services were paid for by any other funding source, then **all** cervical and breast data should be reported in the MDEs.

6. If NBCCEDP does not pay for any of the following clinical services: CBE, pap test, pelvic exam, laboratory services, mammogram, or breast diagnostic procedures, but NBCCEDP funds pay for the cervical diagnostic procedure (e.g., colposcopy), then **only** cervical data should be reported in the MDEs.*

7. If NBCCEDP funds pay for the mammogram and all other clinical services (e.g., pap test, pelvic exam, CBE, cervical and breast diagnostic procedures) are paid by other funds, then **only** breast data should be reported in the MDEs.*

8. If all clinical services (e.g., pap test, CBE, pelvic exam, mammogram, laboratory services, cervical and breast diagnostic procedures) were not paid by NBCCEDP funds, then no data should be reported in the MDEs.

* See the "Reimbursement Policies for Screening and Diagnostic Services," page IV-1, for further guidance on eligibility for these type of services.

Breast data includes CBE, mammogram, breast diagnostic procedures, final diagnosis, stage, tumor size, and treatment initiation information.

Cervical data includes pap test, cervical diagnostic procedures, final diagnosis, stage, and treatment initiation information.

Attachment F: Possible Scenarios

Possible Scenarios for the Cervical Side

Scenario	Pap	DX Workup	Action
1	Paid	Paid	Report all cervical data and pap paid as "Yes." If NBCCEDP paid for the laboratory services, but did not pay for the pap procedure, then pap paid would be coded as "Yes" and all cervical data would be reported. If NBCCEDP paid for the pap procedure but not the laboratory service, then pap paid would be coded as "Yes" and all cervical data should be reported.
2	Paid	Not Paid	Report all cervical data and pap paid as "Yes." If NBCCEDP paid for the laboratory services, but did not pay for the pap procedure, then pap paid would be coded as "Yes" and all cervical data would be reported. If NBCCEDP paid for the pap procedure but not the laboratory service, then pap paid would be coded as "Yes" and all cervical data should be reported.
3	Not Paid	Paid	Report pap result in the Bethesda System and pap paid as "No." If pap result is unknown or pap result is not coded using the Bethesda System, then report pap result as "12 - Result Unknown, Presumed Abnormal, Pap screening from non-program funded source" and pap paid as "No."
4	Not Paid	Not Paid	If cervical screening and diagnostic work-up were performed but paid by other funding sources and breast screening or diagnostic work-up were performed but paid by NBCCEDP funds, then code pap result = "13 - Done recently elsewhere, cervical screening and follow-up services not paid with NBCCEDP funds" and pap paid = "No." The cervical fields would be completed as follows: Previous Pap = "3 - Unknown" Date of Prev Pap = Blank Specimen Adequacy = "4-Unknown" Result of Pap = "13 - Done recently elsewhere, cervical screening and follow-up services ..." Other = Blank Diagnostic Workup Planned = "2 - Diagnostic Workup not Planned" Date of Screening Pap = Blank Pap Paid = "2 - No"

Possible Scenarios for the Breast Side

Scenario	CBE	MAM	DX Workup	Action
1	Paid/ Not Paid	Paid	Paid	Report all breast data and mam paid as "Yes"
2	Paid/ Not Paid	Paid	Not Paid	Report all breast data and mam paid as "Yes"
3	Paid/ Not Paid	Not Paid	Paid	Report mammogram result in BIRADS and mam paid as "No". If mammogram result is unknown or mammogram result is not coded in BIRADS, then report mammogram result as "11 - result unknown, presumed abnormal, mam screening from non program funded source" and mam paid as "No." If clinical breast exam result is available, then report it.
4	Not Paid	Not Paid	Not Paid	If breast screening and diagnostic work-up were performed but paid by other funding sources and cervical screening and diagnostic work-up were performed but paid by NBCCEDP funds, then code mam result as "12 - Done recently elsewhere, breast screening and follow-up services not paid with NBCCEDP funds" and mam paid as "No." The breast fields would be completed as follows: Previous Mammogram = "3 - Unknown" Date Prev Mam = Blank CBE = Not Done Date of CBE = Blank Result of Mam = "12 - Done recently elsewhere, breast screening and follow-up services ..." Diagnostic Workup Planned = "2 - Diagnostic workup Not Planned" Date of Mammogram = Blank Mam Paid = "2 - No"
5	Paid	Not Paid	Not Paid	If office visit is the only service funded and clinical breast exam is included, then all breast data should be reported.

Notes: For Scenarios 1-3 of the Breast Side, clinical breast exam results (if available) should be reported regardless of the payment source.

Paid — NBCCEDP funds were used to pay for the clinical service.

Not Paid — NBCCEDP funds were not used to pay for any part of the clinical service.

Policy for Timeliness and Adequacy of Follow-up for Abnormal Breast and Cervical Cancer Screening

Background

The Breast and Cervical Cancer Mortality Prevention Act of 1990 requires programs to take all appropriate measures to ensure the provision of necessary follow-up services required by women with abnormal screening results. The oversight and management of the surveillance, tracking, and follow-up component of the NBCCEDP continues to be a high priority for the CDC. The CDC policy requires programs to establish and maintain a proactive surveillance system for the timely and appropriate referral and follow-up of women with abnormal or suspicious test results whose clinical services are paid for in whole or in part by the NBCCEDP funds. The DCPC uses the NBCCEDP MDEs to monitor the clinical services provided to women screened through the program. In addition, DCPC has provided programs with the tools discussed below to monitor and assess the timeliness and adequacy of follow-up activities.

Timeliness and Adequacy of Follow-up Algorithm

The algorithm focuses on several specific abnormal screening results and the anticipated clinical interventions based on clinical guidelines endorsed by the Commission on Cancer of the American College of Surgeons, the American College of Obstetrics and Gynecology, and the National Cancer Institute. This tool can be used to identify potential problems with timeliness and adequacy of follow-up of women with abnormal screening tests served by the NBCCEDP.

The timeliness and adequacy algorithm is inappropriate as a tool for clinical decision making for individual women or to determine definitely if individual providers are performing according to accepted community practices. The purpose of the algorithm is to help DCPC and programs monitor the follow-up of women with abnormal screening results served by the NBCCEDP. Programs are advised to consult with their Medical Advisory Committee or Clinical Consultant concerning all clinical decisions. Data that do not meet the minimum guidelines that are outlined in the timeliness and adequacy algorithm will be highlighted in the Submission Audit Reports as presumed inadequate or untimely follow-up.

Submission Narrative Guidelines

The submission narrative provides CDC with written documentation on clinical, programmatic and technical data issues. Following each MDE submission, the CDC Program Consultant and Information Management Services, Inc. (IMS) Technical Consultant will conduct a conference call with each program to discuss program, clinical, and data related issues. The CDC Program Consultant and IMS Technical Consultant will prepare a letter for the program that highlights the action items discussed during the call. Programs should begin each submission narrative by addressing the action items outlined in the letter from the previous submission. Programs should also address the current submission data using these guidelines. The guidelines were mailed to all Program Directors and Data Managers on July 3, 1997.

Submission Audit Report

This Report is intended to improve the reporting of final diagnosis and stage information. The audit report is comprised of line listings by patient ID number, record ID, and enrollment site. IMS updates the audit reports for each submission and include the reports with the routine submission feedback reports. These line listings should be reviewed and missing information should be found and reported in the MDEs by the next submission. The Submission Audit Reports will be mailed to the Program Directors and Data Managers following every submission. Upon receipt of these Reports, programs should investigate the cases and explain the findings in the submission narrative.

DCPC requires programs to adhere to this policy to ensure that NBCCEDP clients with abnormal screening results receive appropriate and timely follow-up services. Attached is a slightly modified version of the timeliness and adequacy algorithm. Programs in need of other referenced items should contact their Program Consultant.

Effective Date

This Policy is effective July 16, 1998 (Federal Fiscal Year 1998).

This algorithm is inappropriate as a tool for clinical decision making in individual women or to determine definitively if individual providers are performing according to accepted community practices.

Introduction

The algorithm focuses on several specific abnormal screening results and the anticipated clinical interventions based on clinical guidelines endorsed by the Commission on Cancer of the American College of Surgeons and the American College of Obstetrics and Gynecology.

Since the MDEs do not include all clinical data, these data alone cannot determine whether clinical guidelines of professional organizations or local standards of care have been followed. However, the algorithm developed at the CDC may be helpful to you to identify potential "red flags" concerning timeliness and adequacy of follow-up of women with abnormal screening tests served by the NBCCEDP. This algorithm is inappropriate as a tool for clinical decision making in individual women or to determine definitively if individual providers are performing according to accepted community practices.

The clinical protocols /guidelines used to develop the algorithm for evaluation and follow-up of abnormal breast and cervical cancer screening tests includes: (1) "Evaluation of common breast problems: A primer for primary care providers," the Society of Surgical Oncology and the Commission on Cancer of the American College of Surgeons; (2) "Cervical cytology evaluation and management of abnormalities ," American College of Obstetricians and Gynecologists (ACOG) technical bulletin entitled (Number 183 - August 1993); (3) "Interim Guidelines for the Management of Abnormal Cervical Cytology," (JAMA 1994;271:1866-9); (4) The Bethesda System (TBS) for reporting Cervical/vaginal cytologic diagnoses (JAMA 1992;267:1892); and (5) the American College of Radiologist's Breast Imaging Reporting and Data System (BI-RADS). Previously, CDC has sent copies of all of these documents to NBCCEDP Program Directors. In this algorithm, we use the term **timely** in relation to the timeliness of follow-up, and **adequate** in relation to adequacy of follow-up.

This algorithm is inappropriate as a tool for clinical decision making in individual women or to determine definitively if individual providers are performing according to accepted community practices.

Cervical Cytology Screening (Pap smears)

Timeliness:

1. If results of screening Pap smear is HSIL or worse then MDE data element 4g2. Diagnostic work-up planned for this Pap smear result should be recorded as "Yes."

2. If results of screening Pap smear is HSIL or squamous cell cancer ($4<g<7$) and the final diagnosis ranges between normal and invasive cervical cancer ($1 \leq b \leq 9$); and the time from Pap smear to final diagnosis is $\leq$ 60 days, then the timeliness of diagnosis is **timely**. If timeliness does not meet these criteria or if data are missing, then timeliness of diagnosis is **not timely**.

3. If results of screening Pap smear is negative through LSIL ($0<g<5$), and work-up is planned, and the final biopsy diagnosis ranges between normal and invasive cervical cancer ($1 \leq b \leq 9$); and the time from Pap smear to final diagnosis is $\leq$ 60 days, then the timeliness of diagnosis is **timely**. If timeliness does not meet these criteria or if data are missing, then timeliness of diagnosis is **not timely**.

4. If results of screening Pap smear is negative or infection/inflammation ($g \leq 4$), and diagnostic work-up is marked "not planned", then no diagnostic work-up is needed for cervical dysplasia or cancer and timeliness need not be assessed. If diagnostic work-up is marked "planned" (abnormal pelvic exam?), then timeliness must be assessed.

5. If screening Pap results = g7-12, then timeliness cannot be assessed.

Adequacy of follow-up:

1. If the result of the screening Pap is negative through LSIL, (g=1-4) and diagnostic work-up is marked "not planned", then adequacy need not be assessed. If work-up is "planned" for negative or infection/inflammation-benign finding results and a colposcopy is performed and a final diagnosis is recorded, then diagnostic follow-up is **adequate**.

2. If the results of the screening Pap smear shows an ASCUS, or low-grade squamous intraepithelial lesion (LSIL), and diagnostic work-up planned is marked "planned"; and if colposcopy with/or without biopsy, has been performed, and final diagnosis is present, then work-up is **adequate**. If diagnostic follow-up does not meet these criteria or if data are missing, then diagnostic follow-up is **not adequate**.

This algorithm is inappropriate as a tool for clinical decision making in individual women or to determine definitively if individual providers are performing according to accepted community practices.

3. If the results of the screening Pap smear show a high grade squamous intraepithelial lesion (HSIL) or squamous cell cancer, and if colposcopy, with/or without biopsy, has been performed, and final diagnosis is present, then work-up is **adequate**. If diagnostic follow-up does not meet these criteria or if data are missing, then diagnostic follow-up is **not adequate**.

4. Adequacy of diagnostic work-up for "other" category cannot be assessed using this data system.

5. The fact that a woman is referred for treatment is NOT sufficient confirmation that treatment has been started. A woman should be classified as having started treatment when the Program has confirmed that a plan for her treatment of the cancer or precancerous lesion has been developed and actually started. The date when treatment started refers to the patient's actual date of surgery or start of therapy.

This algorithm is inappropriate as a tool for clinical decision making in individual women or to determine definitively if individual providers are performing according to accepted community practices.

TIMELINESS and ADEQUACY OF FOLLOW-UP ALGORITHM For Cervical Cancer Screening

Principles:

- **A diagnostic work-up must be planned whenever there is a Pap smear that is HSIL or CxCa.**
- **Whenever a diagnostic work-up is planned, a final diagnosis MUST be recorded for follow-up to be considered adequate.**
- **Whenever a diagnostic work-up is planned, the time from Pap smear to final diagnosis must be no more than 60 days.**

No.	Pap	Diagnostic Procedures	F/U	COMMENTS
1	Neg Inf ASCUS LSIL	No work-up need be planned — Therefore adequacy need not be assessed. If work-up is planned for Neg or Inf results, colposcopy must be done, and a final diagnosis recorded. If work-up planned for ASCUS or LSIL see #2 below.		
2	ASCUS LSIL	If work-up is planned, Colpo or Colpo & Bx	Adeq	Final Diagnosis MUST be present
3	HSIL CxCA	Colpo or Colpo & Bx	Adeq	Final Diagnosis MUST be present
4	Other	Adequacy cannot be assessed		

Abbreviations:

Pap	**Neg =**	**Negative**
	Inf =	**Infection/Inflammation - Benign Finding**
	ASCUS =	**Atypical squamous cells of unknown significance**
	LSIL =	**Low Grade Squamous Intraepithelial lesion**
	HSIL =	**High Grade Squamous Intraepithelial lesion**
	CxCA =	**Squamous carcinoma of the cervix**
	Other =	**Other**
Procedure	**WUPlan =**	**Work-up marked planned**
	Colpo =	**Colposcopy**
	Bx =	**Biopsy**
Follow-up	**Adeq =**	**Adequate**
	Inad =	**Not adequate**

This algorithm is inappropriate as a tool for clinical decision making in individual women or to determine definitively if individual providers are performing according to accepted community practices.

Mammography/Clinical Breast Examination

Timeliness:

1. If the CBE is "abnormality suspicious for cancer" or if the mammography test result is "suspicious abnormality" or "highly suggestive of malignancy", or "assessment is incomplete," then MDE data element 4k1-Diagnostic work-up planned for this CBE/Mammogram should be recorded as "Yes."

2. If a diagnostic work-up is planned on the basis of an abnormal CBE, mammogram or woman's concern, and if either the CBE is "abnormality suspicious for cancer" or the mammography test result is "suspicious abnormality" or "highly suggestive of malignancy" or "assessment is incomplete"; and the time from screening mammogram or CBE (whichever occurs first) to final diagnosis is ≤ 60 days, then timeliness of follow-up is **timely**. If this calculation is >60 days or if the information is missing, then timeliness of follow-up is **not timely**.

3. If the clinical breast exam (CBE) (d) is a normal/benign finding and if the mammography test result is either negative, benign or probably benign short term follow-up suggested, and diagnostic work-up is marked 'not planned', then the diagnostic work-up planned for breast cancer is not needed and timeliness need not be assessed. If work-up is marked "planned", then timeliness must be assessed.

Adequacy of follow-up:

1. If CBE results are normal/benign finding and mammogram results are negative, benign findings, or probably benign/short term follow-up, and diagnostic work-up planned is marked "not planned" then diagnostic follow-up need not be assessed. If, however, for some reason diagnostic work-up is marked planned, if at least one follow-up procedure is performed and a final diagnosis is present, then diagnostic follow-up is **adequate**.

2. If CBE result is "abnormality suspicious for cancer" and mammography test result is "negative, benign finding, probably benign/short term follow-up, or assessment is incomplete," and procedure performed is one or more of: a repeat breast exam (Surgical consult) or ultrasound or biopsy/lumpectomy or fine needle/cyst aspiration, and final diagnosis is present, then diagnostic follow-up is **adequate**. If adequacy does not meet these criteria or if data are missing, then diagnostic follow-up is **not adequate**.

This algorithm is inappropriate as a tool for clinical decision making in individual women or to determine definitively if individual providers are performing according to accepted community practices.

3. If CBE result is "abnormality suspicious for cancer" and mammography test result is either "suspicious abnormality-biopsy should be considered" or "highly suggestive of malignancy," and procedures performed include biopsy/lumpectomy or fine needle/cyst aspiration, and final diagnosis is present, then diagnostic follow-up is **adequate**. If adequacy does not meet these criteria or if data are missing, then diagnostic follow-up is **not adequate**.

4. If CBE result is "normal/benign finding" and mammography test result is "suspicious abnormality-biopsy should be considered," and procedure performed is repeat breast exam, or ultrasound or biopsy/lumpectomy, or fine needle/cyst aspiration (**a.2-a.5**); and final diagnosis is present, then diagnostic follow-up is **adequate**. If adequacy does not meet these criteria or if data are missing, then diagnostic follow-up is **not adequate**.

5. If mammography test result is "highly suggestive of malignancy," and procedures performed include biopsy/lumpectomy or fine needle/cyst aspiration; and final diagnosis is present, then diagnostic follow-up is **adequate**. If adequacy does not meet these criteria or if data are missing, then diagnostic follow-up is **not adequate**.

6. If CBE result is "normal/benign finding" and mammography test result is "assessment incomplete" and procedures performed include additional mammographic views, or ultrasound and final diagnosis is present, then diagnostic follow-up is adequate. If adequacy does not meet these criteria or if data are missing, then diagnostic follow-up is **not adequate**.

7. If CBE result is "abnormality suspicious for cancer" and/or mammography test result is either "suspicious abnormality-biopsy should be considered" or "highly suggestive of malignancy," or "assessment is incomplete," and no final diagnosis is recorded, then diagnostic follow-up is **not adequate**.

8. The fact that a woman is referred for treatment is NOT sufficient confirmation that treatment has been started. A woman should be classified as having started treatment when the Program has confirmed that a plan for her treatment of the cancer or precancerous lesion has been developed and actually started. The date when treatment started refers to the patient's actual date of surgery or start of therapy.

This algorithm is inappropriate as a tool for clinical decision making in individual women or to determine definitively if individual providers are performing according to accepted community practices.

TIMELINESS and ADEQUACY OF FOLLOW-UP ALGORITHM
For Breast Cancer Screening

Principles:

- A diagnostic work-up must be planned whenever there is an abnormal CBE, and/or when the screening mammography result is SA, HSM, or AI.
- Whenever a diagnostic work-up is planned, a final diagnosis MUST be recorded for follow-up to be considered adequate.
- Whenever a diagnostic work-up is planned, the time from screening mammogram or CBE (whichever occurs first) to final diagnosis must be no more than 60 days.

No.	CBE	Mamm[1]	Diagnostic Procedures	F/U	COMMENTS
1	Nor	Neg Ben PB	No work-up need be planned —therefore adequacy need not be assessed. If work-up is planned at least one diagnostic procedure must be done, and a final diagnosis recorded.		
2	Abn	Neg, Ben, PB, AI	≥ 1 (RBE, US, BXL, FNCA)	Adeq	Mamm or AMV as only procedure is not adequate
3	Abn	SA HSM	BXL or FNCA	Adeq	
4	Nor	SA	RBE, US, BXL, FNCA,	Adeq	
5	Nor/Abn	HSM	BXL or FNCA	Adeq	
6	Nor	AI	AMV or US	Adeq	
7	Abn **and/or** (SA or HSM or AI) - if **no** final diagnosis is recorded --> **Inad**				

[1] Screening mammogram if not preceded by suspicious symptoms or abnormal CBE; diagnostic mammogram if post abnormal CBE.

Abbreviations: **CBE = Clinical breast examination Mamm = Mammogram**

CBE
Nor = Normal/Benign Findings
Abn = Abnormality Suspicious for Cancer

Mamm
Neg = Negative
Ben = Benign Finding
PB = Probably Benign - Short-term follow-up
SA = Suspicious Abnormality
HSM = Highly Suggestive of Malignancy
AI = Assessment Incomplete

Procedure
AMV = Additional mammographic views
RBE = Repeat Breast Exam/Surgical Consult
US = Ultrasound
BXL = Biopsy/Lumpectomy
FNCA =Fine Needle/Cyst Aspiration

Follow-up
Adeq = Adequate
Inad = Not adequate

Rescreening Policy and Administrative Requirements

Division of Cancer Prevention and Control
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

Introduction

In 1990, Congress passed the Breast and Cervical Cancer Mortality Prevention Act (Public Law 101-354), authorizing the CDC to establish the NBCCEDP. This legislation enables CDC, in partnership with State and territorial health agencies, tribes, and tribal organizations, to increase access to and use of breast and cervical cancer screening services among low-income women who are uninsured/under-insured. Screening tests provided include clinical breast examinations, mammograms, pelvic examinations, and Papanicolaou smears (Pap smears). Since routine rescreening is needed to see a decrease in mortality from breast and cervical cancers (1,2), a primary objective of the NBCCEDP is to ensure that women are provided mammograms and Pap smears at regular intervals following their initial screening examinations. For the purposes of the NBCCEDP, rescreening is defined as the process of returning for a screening test at a predetermined interval, usually 1 year or greater. This document presents the official CDC program policy regarding rescreening for the NBCCEDP.

Background

Although one screening test may be useful to identify existing cancerous conditions, screening lowers mortality from breast and cervical cancers most effectively if performed at regular intervals (1, 2). The following summarizes the scientific findings and background information regarding recommended intervals for breast and cervical cancer screening.

Breast Cancer/Mammography

Results from clinical trials of breast cancer screening in the 1970s, which compared using mammography with not using mammography, demonstrated a 30 percent reduction in mortality for women 50-69 years of age. The U.S. Preventive Services Task Force recommends that women aged 50 and older undergo mammography screening every 1 to 2 years, and that clinical breast examinations should be performed concurrently with the mammogram (3). The National Cancer Advisory Board recommended the same mammography rescreening schedule for women age 40 and over in March 1997 (4).

The Healthy People 2000 goal related to mammography rescreening established by the Department of Health and Human Services is as follows:

> Increase clinical breast exams and mammography every 2 years to at least 60 percent of women aged 50 and older. (Baseline 25%)

The NBCCEDP follows the National Cancer Advisory Board recommendations; however, because of increased incidence and mortality among older women, the NBCCEDP targets women aged 50 and older. In addition, the NBCCEDP has encouraged programs to utilize medical advisory committees and/or clinical experts to establish screening intervals at the State, territorial, and tribal-level based on provider practice.

Cervical Cancer/Pap smear

Although no organized clinical trials have been conducted using the Pap smear, a large proportion of the decrease in cervical cancer incidence and mortality has been attributed to the use of this screening modality as it detects pre-cancerous lesions as well as invasive carcinoma (5). The American Cancer Society recommends that women who are 18 years of age and older receive an annual Pap smear and pelvic examination. Regular screening is recommended at yearly intervals for 3 years. After three negative screening test results have been recorded, women can be screened less frequently at the discretion of the woman and her provider.

The Healthy People 2000 goal related to Pap smear rescreening established by the Department of Health and Human Services is as follows:

> Increase Pap tests every 1 to 3 years to at least 85 percent of women aged 18 and older. (Baseline 75%).

The NBCCEDP currently follows the American Cancer Society recommendations. Women who have had a hysterectomy are only eligible for NBCCEDP-funded Pap screening if the reason for the hysterectomy was cervical neoplasia.

NBCCEDP Rescreening Data for Mammography and Pap Smears

Review of National program data reported from the MDEs through September 30, 1997, revealed the following rescreening rates[1] for women aged 40 and older for mammograms and for women 20 years and older for Pap smears.

Proportion of Women Receiving a Subsequent NBCCEDP Screening Examination Within the Indicated Time Interval Among the 41 Programs Providing Screening at Least Two Years

	Mammography (Women 40+ years)	Pap Smears (Women 20+ years)
Time from Initial Screen		
18 months	28%	27%
30 months	40%	36%

For 41 programs providing screening tests for at least 2 years, 28% of women who have received a mammogram through the NBCCEDP have returned for at least one subsequent mammogram within 18 months. For 41 programs, twenty-seven percent of women who have received a Pap smear through the NBCCEDP have returned for at least one subsequent Pap smear within 18 months. Forty percent and 36% respectively have returned within 30 months.

Rescreening Policy

Effective January 1, 1999, the following is the official rescreening policy for the NBCCEDP:

(1) Priority for mammograms and Pap smears should be given to **eligible** women previously screened in the NBCCEDP. Age requirements for women provided mammograms through the NBCCEDP are outlined in the Reimbursement Policies for Screening and Diagnostic Services, January 1998.

(2) Specific recommendations for screening intervals for mammography and Pap smears should be established at the State, territorial, tribe, and tribal organization level in consultation with a medical advisory committee and/or clinical experts. At a minimum, these intervals for performing mammography should be consistent with the National Cancer Advisory Board and for Pap smear examinations with the American Cancer Society. Age requirements for women provided NBCCEDP mammograms should be consistent with the Reimbursement Policies for Screening and Diagnostic Services, effective January 1998.

[1]The term "rate" is used in this document as the popular synonym for cumulative incidence or risk. The CDC anticipates that most programs will estimate rescreening proportions, not true rates."

(3) All NBCCEDP-funded programs should develop: (a) an operational plan in consultation with program providers, medical advisory committee and/or clinical experts for rescreening all eligible women who have been previously screened by the program, and (b) specific rescreening protocols.

Components of the operational plan should include:

(A) A description of:
- > the staff who will be responsible for the oversight of the rescreening protocol;
- > the process to monitor the rescreening rates; and,
- > the system to assess the strategies used to assure rescreening.

Components of the rescreening protocol should include:

(A) Counseling women about the purpose of mammography and/or Pap smears when they enroll in the program. Emphasis should be placed on the message that screening at regular intervals leads to a decrease in her risk of dying from breast cancer or developing cervical cancer.

(B) Developing and implementing a reminder system to facilitate the return of women previously screened. The reminder system should be systematic, comprehensive (capturing both mammography and Pap test screening examinations) and applied consistently using acceptable clinical and public health practices. This system should be able to provide documentation that a specific woman has been sent a reminder for rescreening.

Administrative Requirements

(1) All programs must submit a copy of their operational plan and rescreening protocol, outlining the above information for CDC review and approval, in their 1999 continuation or competitive (if applicable) application. The date for the receipt of these applications will be established by the CDC, Procurement and Grants Office (PGO). Programs are encouraged to share draft copies of the operational plan and rescreening protocol with their program consultant prior to submitting the final copy in the continuation or competitive application.

(2) Cooperative agreement recipients should review their rescreening data on a routine basis (e.g. annually). For those programs with an annual (one year) rescreening cycle, the rescreening status of a woman should be assessed 18 months after her prior screening. Programs with a 2 year screening cycle should assess a woman's rescreening status 30 months after her prior screening. CDC will request programs to calculate a rescreening rate and include this rate in their continuation or competitive application. The NBCCEDP

encourages programs, however, to use the Healthy People 2000 goals established by the Department of Health and Human Services as a guide for reviewing mammography and Pap smear rescreening rates. (6)

An external workgroup was organized to develop formulas that will be used to calculate rescreening rates for mammography. These formulas utilize variables that are available in the MDEs submitted to CDC. See Attachment G for a rescreening formula EZ form that will assist programs with calculating a rescreening rate for mammography.

CDC will convene a workgroup to recommend formulas that will be used to calculate rescreening rates for Pap smears. Upon developing these formulas, they will be provided to all NBCCEDP cooperative agreement recipients. CDC recognizes that some programs may have additional data beyond the MDEs available to calculate more informative rescreening rates for their individual programs.

References:

1. Fletcher SW, Black W, Harris R, Rimer BK, Shapiro S. Report of the international workshop on screening for breast cancer. JNCI 1993;85:1644-1656.
2. Shingleton HM, Patrick RL, Johnson WW, Smith RA. The current status of the Papanicolaou smear. CA Cancer J Clin 1995;45:305B20.
3. Screening for breast cancer. In: *Guide to Clinical Preventive Services—Report of the U.S. Preventive Services Task Force.* 2nd ed. Baltimore, Md: Williams and Wilkins;1996:73-87.
4. *Mammography Recommendations for Women Ages 40-49.* Bethesda, Md: National Cancer Advisory Board; 1997:1-5.
5. Screening for cervical cancer. In: *Guide to Clinical Preventive Services—Report of the U.S. Preventive Services Task Force.* 2nd ed. Baltimore, Md: Williams and Wilkins;1996:105-117.
6. Healthy People 2000: National Health Promotion and Disease Prevention Objectives. DHHS Publication No. (PHS) 91-50213, 1990:115.
7. Macharia MW, Leon G, Rowe B, Stephenson B, Haynes BR. An Overview of Interventions to Improve Compliance with Appointment Keeping for Medical Services. JAMA 1992; 267:1813-1817.

Attachment G: Breast Rescreening Formula EZ Forms

Breast Rescreening Formula EZ Form

18 month calculation for Age Group of 50 to 63.5

Program Name: _____

Step 1: Before you start:

A. What is the first day of the "Index" period* you are interested in? (e.g. January 1, 1996) _____

B. What is the last day of the "Index" period you are interested in? (e.g. December 31, 1996) _____

C. How much time do you want to allow for rescreening to be completed? 18 months? 30 months? CDC recommends 18 months and 30 months. (e.g. 18 months) _____

D. What is the latest date that you feel your MDE files are complete, meaning all mammograms up to that date have already been reported and recorded? This date should be at least equal to your response to B plus the length of follow-up time you selected in C. (For example, if the end of your "index" period is December 31, 1996 and you want to allow 18 months for rescreening, you will need to have complete data up to June 30, 1998.) _____

Step 2: Denominator: Total Number of Women age 50 to 63.5 (18 month) found in the "Index" period with a normal/benign mammogram reported in the MDEs (mammogram result of 1 or 2). (Exclude women that are diagnosed with breast cancer as a result of the "Index" mammogram) _____

Step 3: Numerator: Total Number of Women in Step 2 that received another mammogram (reported in the MDEs with a result of 1-6) within the time period allowed. (e.g. for an 18 month calculation the mammogram could have occurred between 0 and 548 days after the date of the "Index" mammogram) _____

Step 4: Calculate Rescreen Rate: Divide Step 3 Total by Step 2 Total and then multiply by 100 _____%

* "Index" period = baseline or reference time. Example: If you want to know the percentage of women in your program *who received a mammogram in 1996* who have been rescreened since that date, then your "index" period is 1996. Each woman in the denominator (Step 2) must have had a mammogram during your "index" period.

National Breast and Cervical Cancer Early Detection Program
Breast Rescreening Formula EZ Form
30 month calculation for Age Group of 50 to 62.5

Program Name: _____

Step 1: Before you start:

A. What is the first day of the "Index" period* you are interested in? _____
(e.g. January 1, 1996)

B. What is the last day of the "Index" period you are interested in? _____
(e.g. December 31, 1996)

C. How much time do you want to allow for rescreening to be _____
completed? 18 months? 30 months?
CDC recommends 18 months and 30 months. (e.g. 30 months)

D. What is the latest date that you feel your MDE files are complete, _____
meaning all mammograms up to that date have already been reported and recorded? This date should be at least equal to your response to B plus the length of follow-up time you selected in C. (For example, if the end of your "index" period is December 31, 1996 and you want to allow 30 months for rescreening, you will need to have complete data up to June 30, 1999.)

Step 2: Denominator: Total Number of Women age 50 to 62.5 (30 month) _____
found in the "Index" period with a normal/benign mammogram reported in the MDEs (mammogram result of 1 or 2). (Exclude women that are diagnosed with breast cancer as a result of the "Index" mammogram)

Step 3: Numerator: Total Number of Women in Step 2 that received _____
another mammogram (reported in the MDEs with a result of 1-6) within the time period allowed. (e.g. for a 30 month calculation the mammogram could have occurred between 0 and 912 days after the date of the "Index" mammogram)

Step 4: Calculate Rescreen Rate: Divide Step 3 Total by Step 2 Total _____%
and then multiply by 100

* "Index" period = baseline or reference time. Example: If you want to know the percentage of women in your program *who received a mammogram in 1996* who have been rescreened since that date, then your "index" period is 1996. Each woman in the denominator (Step 2) must have had a mammogram during your "index" period.

National Breast and Cervical Cancer Early Detection Program
Breast Rescreening Formula EZ Form
18 month calculation for Age Group of 40 to 49

Program Name: _____

Step 1: Before you start:

A. What is the first day of the "Index" period* you are interested in? _____
(e.g. January 1, 1996)

B. What is the last day of the "Index" period you are interested in? _____
(e.g. December 31, 1996)

C. How much time do you want to allow for rescreening to be _____
completed? 18 months? 30 months?
CDC recommends 18 months and 30 months. (e.g. 18 months)

D. What is the latest date that you feel your MDE files are complete, _____
meaning all mammograms up to that date have already been reported and recorded? This date should be at least equal to your response to B plus the length of follow-up time you selected in C. (For example, if the end of your "index" period is December 31, 1996 and you want to allow 18 months for rescreening, you will need to have complete data up to June 30, 1998.)

Step 2: Denominator: Total Number of Women age 40 to 49 found _____
in the "Index" period with a normal/benign mammogram reported in the MDEs (mammogram result of 1 or 2). (Exclude women that are diagnosed with breast cancer as a result of the "Index" mammogram)

Step 3: Numerator: Total Number of Women in Step 2 that received _____
another mammogram (reported in the MDEs with a result of 1-6) within the time period allowed. (e.g. for an 18 month calculation the mammogram could have occurred between 0 and 548 days after the date of the "Index" mammogram)

Step 4: Calculate Rescreen Rate: Divide Step 3 Total by Step 2 Total _____%
and then multiply by 100

* "Index" period = baseline or reference time. Example: If you want to know the percentage of women in your program *who received a mammogram in 1996* who have been rescreened since that date, then your "index" period is 1996. Each woman in the denominator (Step 2) must have had a mammogram during your "index" period.

National Breast and Cervical Cancer Early Detection Program
Breast Rescreening Formula EZ Form
30 month calculation for Age Group of 40 to 49

Program Name: _____

Step 1: Before you start:

A. What is the first day of the "Index" period* you are interested in? _____
(e.g. January 1, 1996)

B. What is the last day of the "Index" period you are interested in? _____
(e.g. December 31, 1996)

C. How much time do you want to allow for rescreening to be _____
completed? 18 months? 30 months?
CDC recommends 18 months and 30 months. (e.g. 30 months)

D. What is the latest date that you feel your MDE files are complete, _____
meaning all mammograms up to that date have already been reported and recorded? This date should be at least equal to your response to B plus the length of follow-up time you selected in C. (For example, if the end of your "index" period is December 31, 1996 and you want to allow 30 months for rescreening, you will need to have complete data up to June 30, 1999.)

Step 2: Denominator: Total Number of Women age 40 to 49 found _____
in the "Index" period with a normal/benign mammogram reported in the MDEs (mammogram result of 1 or 2). (Exclude women that are diagnosed with breast cancer as a result of the "Index" mammogram)

Step 3: Numerator: Total Number of Women in Step 2 that received _____
another mammogram (reported in the MDEs with a result of 1-6) within the time period allowed. (e.g. for a 30 month calculation the mammogram could have occurred between 0 and 912 days after the date of the "Index" mammogram)

Step 4: Calculate Rescreen Rate: Divide Step 3 Total by Step 2 Total _____%
and then multiply by 100

* "Index" period = baseline or reference time. Example: If you want to know the percentage of women in your program *who received a mammogram in 1996* who have been rescreened since that date, then your "index" period is 1996. Each woman in the denominator (Step 2) must have had a mammogram during your "index" period.

Case Management Policy
National Breast and Cervical Cancer Early Detection Program

Background

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is a landmark program that brings critical breast and cervical cancer screening services to medically underserved women and ethnic minorities who are low income. The purpose of the program is to reduce morbidity and mortality from breast and cervical cancers. Fiscal Year 2000 represents the tenth year of the NBCCEDP.

A crucial component of the NBCCEDP is to ensure that women with abnormal screening results or who have a diagnosis of cancer receive the follow-up services they need. However, the legislation that authorizes the NBCCEDP does not allow resources appropriated for the program to be used for treatment. In fulfilling this component, participating health agencies are required to identify and secure resources for cancer treatment services for women in need, regardless of their ability to pay. In 1997, CDC funded a study of follow-up and treatment issues in the NBCCEDP. This study revealed the importance of expanding case management to develop and sustain a network of clinical and essential support services for women served through the program. The establishment of the network is necessary to ensure that women with abnormal screening results or with a diagnosis of cancer receive appropriate and timely services (1).

The legislation that originally authorized the establishment of the NBCCEDP, the Breast and Cervical Cancer Mortality Prevention Act of 1990 (P.L. 101-354), did not specifically reference case management as a program component. However, in October 1998, Congress modified the legislative authority of the program to include case management. The amendment, contained in the Women's Health Research and Prevention Amendments of 1998, states, "...to ensure, to the extent practicable, the provision of appropriate follow-up services **and support services such as case management...** (2)**"**

With this new legislative change, CDC has examined the range of support services currently being provided through the NBCCEDP, from one-on-one outreach, to tracking and follow-up, to case management. These services, as they address women targeted for the program, all fall within the 60 percent distribution and comprise a continuum of care that begins with individual outreach and moves toward the most intensive intervention, case management. Although each of these services is unique and distinct, CDC recognizes the important relationship among these different support services. For instance, one-on-one outreach is crucial in recruiting eligible women into the program who would then need tracking and potentially be assessed to need case management.

In consultation with a work group comprised of case management experts, NBCCEDP program directors, consultants, and staff, the CDC has developed a comprehensive policy on case

management for the NBCCEDP. This policy provides programmatic guidance to all NBCCEDP-funded programs. It is not intended to be a set of case management practice guidelines for other public health programs or health care settings. The issues covered by this policy include the:

- goal and definition of case management for the NBCCEDP;
- key elements of case management at the program and individual levels;
- policy statements; and
- administrative requirements for NBCCEDP-funded programs.

NBCCEDP-funded programs should use the elements outlined in this policy when developing new or expanding existing case management activities. CDC recognizes that individual programs will implement case management differently, taking into account local and regional needs, program resources, and population characteristics.

Goal and Definition of Case Management

The goal of case management for the NBCCEDP is to ensure that women enrolled in the program receive timely and appropriate rescreening, diagnostic, and treatment services. Assessment of NBCCEDP-enrolled women for case management services and the provision of such services when necessary should assist in attaining this goal. The effect of case management and the progress toward reaching this goal initially will be measured by the Policy for Timeliness and Adequacy of Follow-up for Abnormal Breast and Cervical Cancer Screening in this Section of the Manual and the MDE Data Quality Indicator Guide.

Case management is defined for the NBCCEDP as a program component that involves establishing, brokering, and sustaining a system of available clinical (screening, diagnostic, and treatment) and essential support services for all NBCCEDP-enrolled women who would ultimately be assessed to need case management services. Throughout this policy, the term “client” refers to women in the NBCCEDP who have a demonstrated need for case management (see Policy #1, page 10), the most intensive intervention in the continuum of care. CDC expects that the proportion of case management clients in the program will be small compared with all the women being served by the NBCCEDP.

CDC recognizes that some programs are currently providing support services and may be defining those activities as case management. However, those activities may not meet the definition of case management delineated throughout this policy. These services may be better defined as outreach, tracking, or follow-up services. The intent of this policy is to better define and differentiate case management from the other, less intensive, support services. To accomplish this goal, professional standards of case management should be applied to this important program component to assure that NBCCEDP-enrolled women become, as needed, case management clients to better facilitate their access to rescreening, diagnostic, and treatment services.

Key Elements of Case Management

Key elements of the case management component at both the program and client levels include assessment, planning, coordination, monitoring, evaluation, and resource development. At the program level (e.g., state, tribal, regional, local offices and ministries of health) the implementation of all key elements is intended to assure collaborative case management planning and infrastructure enhancement. At the client level, the elements represent a cooperative process between the client and provider intended to assure timely rescreening, diagnostic, and treatment services.

The elements outlined in this policy may not include all possible functions of a case management system; however, they are the minimum elements to be incorporated into NBCCEDP case management activities. These key elements are not listed in chronological order. All case management elements are interdependent and build on one another. For example, an assessment must be done before a case management plan can be developed. In addition, there is no distinct start or end point for each element. Depending on the needs of the client, some elements will extend throughout the process, such as resource development, and others may only occur once throughout the entire case management process, such as coordination of one specific service for the client.

These elements have been adapted from individual standards and guidelines published by the Case Management Society of America (CMSA), the National Association of Social Workers (NASW), and the National Center for HIV, STD, and TB Prevention, CDC (NCHSTP) as well as a review of the published literature on case management.

Key Element	Program/Systems Definition	Individual Client Definition
Assessment	The determination of the programs' need for and preparedness to implement, oversee, and manage a case management system. Major activities of this assessment may include the following: appraisal of available community resources; assessment of the need for case management services among NBCCEDP-enrolled women; examination of staff and agency capacity for providing case management; and utilization of existing provider services.	A cooperative effort between the client and case manager to examine the client's need for rescreening, diagnostic, treatment, and essential support services through a process of gathering critical information from the client. This assessment should include consent and assurance of confidentiality between the client, the case manager and the provider team. Such consent and assurance should be documented in the client's medical records.
Planning	The overall assurance that program resources are available to meet the needs of individual clients. This may entail determining how many clients may be eligible for case management services, assessing provider preparedness, defining a beginning and ending point for the delivery of case management services, determining activities for each key element, developing relevant protocols and program materials, and defining accountability for the execution of case management activities.	The development of an individual client plan for meeting immediate, short-term and long-term needs, as identified in the assessment. The written plan should set goals and related activities with time frames, as well as delineate who is responsible for meeting what goals. It is important that the client plan is consistently revisited throughout the case management process.

Coordination	The establishment of standardized systems to track various aspects of case management. Suggestions include: the development of a standardized written referral process; the establishment of relationships and communication between case managers in different organizations to avoid duplication of services and to optimize services for the client; and, the management of a referral tracking system.	The brokerage, coordination, and referral of services to meet the needs of the client as outlined in the client plan. Provision of active assistance by the case manager to ensure that the client receives the services identified in the client's plan. Steps taken to coordinate service needs should be documented in the client plan.
Monitoring	The re-assessment and, if necessary, the re-design of the programs' case management systems and operational plan.	The ongoing re-assessment of the client's needs. The re-assessment of the quality of care and services provided to the client to determine if new and continuing needs are being met. Client plans should be updated based on routine re-assessments.
Resource Development	The establishment of formal and informal agreements to maximize availability and access to essential screening support services, diagnostic and treatment resources.	Promoting self-sufficiency and self-determination among clients by assuring that women gain the knowledge, skills and support needed to obtain necessary services.
Evaluation	The process of assessing the effectiveness of the overall case management system as developed by the program. This should include developing outcome measures that at a minimum measure the timeliness and adequacy of individual case management services, case management provider satisfaction, and effectiveness of referral systems. These measures should be tied to the Minimum Data Elements (MDEs). (See section E of the Program Progress Review in the Policies and Procedures Manual.)	The process of assessing client satisfaction, access and timeliness of referral services, and the quality of individual case management client plans.

Case Management Policy

1. A. All NBCCEDP-enrolled women with an abnormal screening result or with the diagnosis of cancer must be assessed for their need of case management services and provided such services accordingly.

Women with an abnormal screening result or with a diagnosis of cancer are the priority population to receive case management services. Abnormal screening results are defined in the NBCCEDP Data User's Manual and are also listed below:

- Clinical Breast Exam - Abnormal, suspicious for cancer. This includes clinical categories: (3) discrete palpable mass; (4) bloody or serous nipple discharge; (5) nipple or areolar scaliness; and (6) skin dimpling or retraction.
- Mammography - Abnormal results include American College of Radiology (ACR) categories: (4) suspicious abnormality, biopsy should be considered; (5) highly suggestive of malignancy, appropriate action should be taken; and (6) assessment is incomplete, need additional imaging evaluation.
- Pap Test - Abnormal results include high-grade squamous intraepithelial lesion (HSIL) and squamous cell carcinoma.

B. As staffing and fiscal resources allow, additional circumstances for which expanding the initiation of case management services could include:

- lack of response to rescreening reminder system after normal screen;
- previous history of abnormal screening results;
- results requiring short-term follow-up (e.g. ASCUS, LSIL, ACR 3 - probably benign, short interval follow-up indicated);
- lack of timely response at any stage of the screening and diagnosis process; and
- request by the client or provider.

C. Case management services should conclude when a client initiates treatment or is no longer eligible for the NBCCEDP. Programs may give consideration to continuing case management services beyond the initiation of treatment based on the client's demonstration of need, as staffing and fiscal resources allow.

D. Clients should be re-assessed for case management upon receipt of rescreening results. Tracking and follow-up and reminder systems should be in place to ensure that a client returns for rescreening (see Rescreening Policy and Administrative Requirements in the Policies and Procedures Manual).

2. All NBCCEDP-funded programs should develop an operational plan for case management. Programs are encouraged to consult with program providers and NBCCEDP staff in developing the operational plan. CDC program consultants are available to provide technical assistance. The operational plan should include:

- goals and objectives for case management component;
- a description of planned activities for each key element of the case management process (assessment, planning, coordination, monitoring, resource development, and evaluation);
- the staff who will be responsible for the oversight of case management activities (see sample case management standards for suggested case manager skill sets, e.g. CMSA);
- the process to monitor the case management activities at the NBCCEDP-funded sites and other organizations to which case management responsibilities are delegated;
- the process to assess the overall effectiveness of case management;
- a timeline for implementing a new system of case management or enhancing an existing system; and
- a description of the reimbursement system for case management activities.

3. The NBCCEDP-funded program should maintain ultimate accountability and responsibility for assuring case management activities. Case management can be delegated to other organizations/providers with a formal written agreement. This agreement should specify partners' responsibilities and the system of monitoring to be implemented. A copy of this agreement should be included with the operational plan. If delegation of case management occurs, the minimum key elements of case management outlined in this policy must be maintained.

Administrative Requirements

1. All programs must submit a copy of their operational plan and budget with a justification to CDC, outlining the above information for review and approval. For assistance in developing the operational plan, programs should refer to the sample case management standards for guidance (CMSA, NASW, HIV Prevention Case Management Guidance). Programs should indicate what model was used in their development process. Programs are encouraged to share draft copies of the operational plan and budget with a justification with their program consultant prior to submitting the final copy.

2. NBCCEDP funds may be used to reimburse for case management services. Delivery of case management services is considered an essential screening support service and falls within the 60 percent distribution ("essential screening support services" are outlined in Section II of the Policies and Procedures Manual).

Effective Date

This policy is effective October 1, 1999.

References

1. Centers for Disease Control and Prevention (CDC). Strategies for Providing Follow-Up and Treatment Services in the National Breast and Cervical Cancer Early Detection Program - United States, 1997. Morbidity and Mortality Weekly Report (MMWR) 1997; 47: 215-18.

2. Women's Health Research and Prevention Amendments, Public Law 105-340, signed October 31, 1998.

3. CDC. HIV Prevention Case Management Guidance, September, 1997.

4. National Association of Social Workers (NASW). NASW Standards for Social Work Case Management, June 1992.

5. Case Management Society of America (CMSA). Standards of Practice for Case Management, 1995.

Revision date: 9/30/1999

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A sample Financial Status Report,
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http://www.acf.dhhs.gov/programs/oa/form.htm

Human Subjects/Institutional Review Board Information

Policies and Procedures for Protecting Human Research Participants in CDC-Funded Research

General

All funded research (whether through grants, cooperative agreements, contracts, or purchase orders) must comply with the Federal regulations for protecting human participants found in Title 45 Code of Federal Regulations (CFR) Part 46. The Procurement and Grants Office (PGO) will ensure that all external collaborating sites in a research study have assurances and institutional review board (IRB) approval for the proposed research **before** the research is initiated. PGO has the option of either holding the award or making the award and restricting funds from expenditure on human participants until all Federal requirements are met as specified in 45 CFR 46. PGO will make this determination on a case by case basis.

It is the responsibility of the CIO Human Subjects Contact (HSC)* to inform PGO whether a proposed study is research that involves human participants, whether CDC staff are participating in the research as co-investigators, and if any exemptions are claimed. It is also the Human Subjects Contact's responsibility for ensuring that CDC IRB approval is determined where CDC staff are participating in the research.

Grants/Cooperative Agreements

For those programs involving research where humans are expected to be participants, the HSC must make certain the following language is included in the Human Subjects subpart of the Other Requirements section in the program announcement:

> "If the proposed project involves research on human participants, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR 46) regarding the protection of human research participants. Assurance must be provided to demonstrate that the project will be subject to initial and continuing reviews by an appropriate institutional review board. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit."

If CDC scientists will be co-investigators in the research project, the HSC must make certain the following insert related to obtaining CDC IRB approval is included under the CDC Activities listed under the Program Requirements section in the program announcement:

> "Assist in the [e.g., design of the study, design of the instruments, development of methods and procedures for the study, collection of the data, analysis of the data, interpretation of the data, or co-authorship of the paper] for IRB review by all institutions participating in the research project.
>
> The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed."

To verify that the HSC has reviewed the program announcement and included all appropriate language in the announcement if humans are expected to be participants in the research, the HSC must sign the certification of available funds document (CDC 0.1067 form) which must be submitted to GMB, PGO when the final version of the program announcement is submitted.

When CIOs submit funding memoranda for new and continuation awards, they must attach to the memorandum, the "Tracking Form for Research Funded Through CDC Grants and Cooperative Agreements" which indicates whether humans will be participating as subjects in the proposed research award. The form will also identify if CDC scientists will be co-investigators; and if so, whether the CDC IRB has reviewed and approved the protocol. The form is to be signed and dated by the HSC. If an exemption is claimed under 46.101, GMB, PGO will promptly forward the tracking form to the Deputy Associate Director for Science for concurrence.

For all research awards involving humans as participants, GMB, PGO will enter one or more of the following codes into the award module of the Grants Management Information System (GMIS):

30 - human subjects - one site
33 - human subjects - multiple sites
36 - human subjects - multiple sites including CDC as one of the sites

40 - awardee missing an assurance or certification
43 - any of the participating sites missing assurances or certifications
46 - certification missing for CDC

Contracts/Purchase Orders

> <u>When research is developed in the first phase and conducted in the second phase of a contract</u>:
>
> At the time the RFC is submitted to PGO, the CIO HSC** informs PGO that the study is research involving humans as participants, indicates whether CDC investigators are

involved, and whether an exemption is claimed. Funds are not restricted for phase one. Phase two cannot begin (i.e. funds are restricted or approval to proceed to phase two is withheld) until all assurances and IRB approvals are obtained. If CDC investigators are participating in the research, the CIO HSC must inform PGO of CDC IRB approval before approval is given to the contractor to proceed with phase two.

When the research protocol is described in the RFC:

CIO HSC** informs PGO that the study is research involving humans as participants, whether CDC investigators are participating in the research, and if an exemption is claimed. If CDC investigators are participating, the CDC IRB must approve the research before the award is made. The CIO HSC informs PGO that research is approved by CDC IRB.

**The HSC completes, signs and dates the "Clearance Checksheet for Contracts" form and submits it with the RFC.

In addition to the standard language pertaining to research involving human participants, the Request for Proposal (RFP) will contain the following language when CDC scientists are to be involved as co-investigators in the contract:

"CDC's Institutional Review Board (IRB)

It is anticipated that this requirement will involve participation by CDC investigators in the research activities. Therefore, the CDC IRB must approve the research protocol prior to contract award. If the CDC IRB approval is not received prior to contract award then a restricted award can be made. Contract awards issued on a restricted basis will prohibit the use of any funds that are associated with the use of human subjects."

In addition to the standard language pertaining to research involving human participants, the contract will contain the following language when CDC investigators are to be involved as investigators and the CDC IRB has not met prior to award:

"Notice of Restricted Award Pending CDC Institutional Review Board (IRB) Approval

It has been determined that this requirement will involve participation by CDC investigators in the research activities; therefore, the CDC IRB is required to approve the protocol prior to beginning any tasks or using Federal funds that involve human subjects. Once the CDC IRB approval of the protocol is rendered, the Contracting Officer will provide written notification removing the award restriction."

Grants/Cooperative Agreements/Contracts

PGO will promptly send all research tracking forms and clearance checksheets that identify exempted research to the Deputy Associate Director for Science for concurrence.

Special Notes:

All determinations that research is exempt from IRB review, whether for a grant, a cooperative agreement, a contract, or a purchase order must be reviewed and approved by the Deputy Associate Director for Science. This includes determinations made by CIO HSCs, by awardee IRBs, or by other participating organization IRBs. The research tracking form or checksheet must be completed, signed, and dated by the HSC. Upon receipt, PGO will promptly send the tracking form or checksheet to the Deputy Associate Director for Science for concurrence.

If a CIO does not provide all the required human subjects information to PGO, PGO will assume that any proposed activity involving data collection is research and CDC investigators are participating in the study and the project is therefore subject to the human subjects regulations.

Disagreements between a CIO HSC and PGO involving whether research is subject to the human subjects regulations or whether the project is exempt from IRB review, etc. will be resolved by the Deputy Associate Director for Science who should be contacted immediately by either party by e-mail, telephone, or memorandum with notification to the other party.

*A Human Subjects Contact is a person designated by the CIO to serve as the liaison with the human subjects office at CDC. The Human Subjects Contact is generally the Associate Director for Science or a specific designee. A list of human subjects contacts is maintained by the Deputy Associate Director for Science and is located on the Associate Director for Science Intranet homepage.

CODE OF FEDERAL REGULATIONS
TITLE 45
PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS
PART 46
PROTECTION OF HUMAN SUBJECTS

* * *

Revised June 18, 1991
Effective August 19, 1991

* * *

Subpart A -- Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)

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Authority: 5 U.S.C. 301; Sec. 474(a), 88 Stat. 352 (42 U.S.C. 2891-3(a)).
Note: As revised, Subpart A of the DHHS regulations incorporates the Common Rule (Federal Policy) for the Protection of Human Subjects (56 FR 28003). Subpart D of the HHS regulations has been amended at Section 46.401(b) to reference the revised Subpart A.
The Common Rule (Federal Policy) is also codified at

7 CFR Part 1c	**Department of Agriculture**
10 CFR Part 745	**Department of Energy**
14 CFR Part 1230	**National Aeronautics and Space Administration**
15 CFR Part 27	**Department of Commerce**
16 CFR Part 1028	**Consumer Product Safety Commission**
22 CFR Part 225	**International Development Cooperation Agency,Agency for International Development**
24 CFR Part 60	**Department of Housing and Urban Development**
28 CFR Part 46	**Department of Justice**
32 CFR Part 219	**Department of Defense**
34 CFR Part 97	**Department of Education**
38 CFR Part 16	**Department of Veterans Affairs**
40 CFR Part 26	**Environmental Protection Agency**
45 CFR Part 690	**National Science Foundation**
49 CFR Part 11	**Department of Transportation**

TITLE 45
CODE OF FEDERAL REGULATIONS
PART 46
PROTECTION OF HUMAN SUBJECTS

* * *

Revised June 18, 1991
Effective August 19, 1991

* * *

Subpart A	**Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)**
	Source: 56 FR 28003, June 18, 1991.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each Department or Agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal Department or Agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal Department or Agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an Institutional Review Board (IRB) thatoperates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:[1]

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or
(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food isconsumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
(c) Department or Agency heads retain final judgment as to whether a particular activity is covered by this policy.
(d) Department or Agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Department or Agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.
(e) Compliance with this policy requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.
(f) This policy does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.
(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.
(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by

sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a Department or Agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the Department or Agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the Department or Agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in Department or Agency procedures.

(i) Unless otherwise required by law, Department or Agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the Department or Agencyhead shall forward advance notices of these actions to the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services (DHHS), and shall also publish them in the **Federal Register** or in such other manner as provided in Department or Agency procedures.[1]

[1] Institutions with DHHS-approved assurances on file will abide by provisions of Title 45 CFR Part 46 Subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

§46.102 Definitions.

(a) *Department or Agency* head means the head of any Federal Department or Agency and any other officer or employee of any Department or Agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or Agency (including Federal, State, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a Federal Department or Agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentallyregulated

by a Federal Department or Agency solely as part of the Department's or Agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).
(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains
(1) data through intervention or interaction with the individual, or
(2) identifiable private information.
Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
(g) *IRB* means an Institutional Review Board established in accord with and for the purposes expressed in this policy.
(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.
(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
(j) *Certification* means the official notification by the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§46.103 Assuring compliance with this policy -- research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a Federal Department or Agency shall providewritten assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual Department or Agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, National Institutes Health, DHHS, and approved for Federalwide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to Department and Agency heads shall also be made to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Department or Agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to Department- or Agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Department or Agency head, unless in accord with §46.103(a) of this policy, the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the Department or Agency head prescribes.

(d) The Department or Agency head will evaluate all assurances submitted in accordance with this

policy through such officers and employees of the Department or Agency and such experts or consultants engaged for this purpose as the Department or Agency head determines to be appropriate. The Department or Agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Department or Agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Department or Agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a Federal Department or Agency and not otherwise exempted or waived under §46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the Department or Agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the Department or Agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§§46.104--46.106 [Reserved]

§46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so

long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB

§46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:
(a) Follow written procedures in the same detail as described in §46.103(b)(4) and to the extent required by §46.103(b)(5).
(b) Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting

§46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.
(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the **Federal Register**, a list

of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Department or Agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent

required by §46.117.
(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the Department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
(3) Records of continuing review activities.
(4) Copies of all correspondence between the IRB and the investigators.
(5) A list of IRB members in the same detail as described in §46.103(b)(3).
(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and

§46.103(b)(5).
(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).
(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:
(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
(2) a description of any reasonably foreseeable risks or discomforts to the subject;
(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;
(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
(b) additional elements of informed consent. When appropriate, one or more of the following

elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's

legally authorized representative. A copy shall be given to the person signing the form.
(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Department or Agency.

§46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is

later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the Department or Agency, and final approval given to the proposed change by the Department or Agency.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The Department or Agency head will evaluate all applications and proposals involving human subjects submitted to the Department or Agency through such officers and employees of the Department or Agency and such experts and consultants as the Department or Agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the Department or Agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§46.121 [Reserved]

§46.122 Use of Federal funds.

Federal funds administered by a Department or Agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The Department or Agency head may require that Department or Agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Department or Agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the Department or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Department or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

§46.124 Conditions.

With respect to any research project or any class of research projects the Department or Agency head may impose additional conditions prior to or at the time of approval when in the judgment of the Department or Agency head additional conditions are necessary for the protection of human subjects.

Subpart B	**Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization**
	Source: 40 FR 33528, Aug. 8, 1975; 43 FR 1758, January 11, 1978; 43 FR 51559, November 3, 1978.

§46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services (DHHS) to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the **Federal Register** guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these Board(s) shall be so selected that the Board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No Board member may be a regular, full-time employee of the Department of Health and Human Services.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class ofapplications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) *[Nullified under Public Law 103-43, June 10, 1993]*

§46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) determine that all aspects of the activity meet the requirements of this subpart;

(2) determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in §46.120 of Subpart A

of this part.
(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:
(1) appropriate studies on animals and nonpregnant individuals have been completed;
(2) except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity;
(3) individuals engaged in the activity will have no part in: (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and
(4) no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.
(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

Source: 40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975.

§46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.
(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§46.208 Activities directed toward fetuses *in utero* as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs ofthe particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.
(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§46.209 Activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus *ex utero* is viable, a fetus *ex utero* may not be involved as a subject in an activity covered by this subpart unless:

(1) there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) vital functions of the fetus will not be artificially maintained,

(2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) heis not reasonably available, or (3) the pregnancy resulted from rape.

§46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the **Federal Register**.

Subpart C	**Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects**
	Source: 43 FR 53655, Nov. 16, 1978.

§46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.
(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.
(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it

§46.303 Definitions.

As used in this subpart:
(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
(b) "DHHS" means the Department of Health and Human Services.
(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which providealternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:
(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) the research under review represents one of the categories of research permissible under

§46.306(a)(2);
(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
(3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
(5) the information is presented in language which is understandable to the subject population;
(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
(7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.
(b) The Board shall carry out such other duties as may be assigned by the Secretary.
(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) the institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

(2) in the judgment of the Secretary the proposed research involves solely the following:

(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
(B) study of prisons as institutional structures or of prisoners asincarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
(C) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological

problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of his intent to approve such research; or

(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D	**Additional DHHS Protections for Children Involved as Subjects in Research**
	Source: 48 FR 9818, March 8, 1983; 56 FR 28032, June 18, 1991.

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (i) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

§46.402 Definitions.

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as

used in this subpart:
(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.
(d) "Parent" means a child's biological or adoptive parent.
(e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:
(a) the risk is justified by the anticipated benefit to the subjects;
(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
(c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:
(a) the risk represents a minor increase over minimal risk;
(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
(d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

DHHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:
(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following:

(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
(ii) the research will be conducted in accordance with sound ethical principles;
(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.
(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407 and permission is to be obtained from parents, both parents must

give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of anappropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.
(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:
(1) related to their status as wards; or
(2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Guidelines for Defining Public Health Research and Public Health Non-Research
Revised October 4, 1999

PURPOSE

The Centers for Disease Control and Prevention (CDC) is committed to preventing disease and injury and improving health for all Americans. CDC is also committed to protecting individuals who participate in all public health activities. In the conduct of public health research, CDC follows the Code of Federal Regulations, Title 45, Part 46, The Public Health Service Act as amended by the Health Research Extension Act of 1985, Public Law 99-158, which sets forth regulations for the protection of human subjects.

This document, *Defining Public Health Research and Public Health Non-Research*, sets forth CDC guidelines on the definition of public health research conducted by CDC staff irrespective of the funding source (i.e., provided by CDC or by another entity). Under Federal regulations (45 CFR 46), the final determination of what is research and whether the Federal regulations are applicable lies with CDC and, ultimately, with the Office for Protection from Research Risks (OPRR). Thus, this document is intended to provide guidance to state and local health departments and other institutions that conduct collaborative research with CDC staff or that are recipients of CDC funds. The guidelines are intended to ensure both the protection of human subjects and the effective practice of public health.

BACKGROUND

In 1974, the Department of Health and Human Services (formerly the Department of Health, Education and Welfare) developed regulations to assure the protection of human subjects from research risks. These regulations were developed to address ethical issues raised in connection with biomedical or behavioral research involving human subjects. Because most biomedical research is funded by the National Institutes of Health (NIH), the regulations were developed to deal specifically with the types of research funded by NIH. The regulations have been revised several times; currently the Department is operating under Title 45 Code of Federal Regulations Part 46, 1991 revision. The regulations will be referred to as 45 CFR 46.

The practice of public health poses several challenges in implementing 45 CFR 46. Although some public health activities can unambiguously be classified as either research or non-research, for other activities the classification is more difficult. The difficulty in classifying some public health activities as research or non-research stems either from traditionally held views about what constitutes public health practice or from the fact that 45 CFR 46 does not directly address many

public health activities. In addition, the statutory authority of state and local health departments to conduct public health activities using methods similar to those used by researchers is not recognized in the regulations. Human subject protections applicable for activities occurring at the boundary between public health non-research and public health research are not readily interpretable from the regulations.

The regulations state that "research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Obtaining and analyzing data are essential to the usual practice of public health. For many public health activities, data are systematically collected and analyzed, blurring the distinction between research and non-research. Scientific methodology is used both in non-research and research activities that comprise the practice of public health. Because scientific principles and methodology are applied to both non-research and research activities, knowledge is generated in both cases. Furthermore, at times the extent to which that knowledge is generalizable may not differ greatly in research and non-research. Thus, non-research and research activities cannot be easily defined by the methods they employ. Three public health activities - surveillance, emergency responses, and evaluation - are particularly susceptible to the quandary over whether the activity is research or non-research.

The key word in the regulations' definition of research for the purpose of classifying public health activities as either research or non-research is "designed." The major difference between research and non-research lies in the primary intent of the activity. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of non-research in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. Knowledge may be gained in any public health endeavor designed to prevent disease or injury or improve a program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered.

Classifying an activity as research does not automatically lead to review by an institutional review board (IRB) for the protection of human subjects. Once an activity is classified as research, two additional determinations must be made: (1) does the research involve human subjects and, if so, (2) does the research meet the criteria for exemption from IRB review. This policy deals only with the first determination of whether a public health activity is research or non-research.

DEFINITIONS

Research - As defined in 45 CFR 46, research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Human Subjects - As defined in 45 CFR 46, a human subject means "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

Surveillance - The ongoing, systematic collection, analysis, and interpretation of outcome-specific data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury (Thacker and Berkelman, 1988).

Emergency Response - A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, 1980).

Program Evaluation – An essential organizational practice in public health using a systematic approach to improve and account for public health actions (Centers for Disease Control and Prevention, 1999)

Evaluation - The systematic application of scientific and statistical procedures for measuring program conceptualization, design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes (Rossi and Freeman, 1993; Fink, 1993).

POLICY

CDC is required to and has an ethical obligation to ensure that individuals are protected in all public health research activities it conducts. All CDC activities must be reviewed to determine whether they are research involving human subjects. When an activity is classified as research involving human subjects, CDC and its collaborators will comply with 45 CFR 46 in protecting human research subjects.

Some surveillance projects, emergency responses, and evaluations are research involving human subjects; others are not. Each project must be reviewed on a case-by-case basis. Although general guidance can be given to assist in classifying these activities as either research or non-research, no one criterion can be applied universally. The ultimate decision regarding classification lies in the intent of the project. If the primary intent is to generate generalizable knowledge, the project is research. If the primary intent is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is non-research. If the primary intent changes to generating generalizable knowledge, then the project becomes research.

GUIDANCE FOR COMPLIANCE

I. General

The Human Subjects Contact (HSC) in each Center, Institute, or Office (CIO) determines whether the project constitutes research. If the HSC is unclear about classifying a project, the HSC should consult with the CDC's Deputy Associate Director for Science. This determination is made by examining the intent of the project. What is the primary purpose for which the project was designed?

General Attributes of Public Health Research - Intent of the project is to generate generalizable knowledge to improve public health practice; intended benefits of the project may or may not include study participants, but always extend beyond the study participants, usually to society; and data collected exceed requirements for care of the study participants or extend beyond the scope of the activity. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected. Generalizable, for purposes of defining research, does not refer to the statistical concept of population estimation or to the traditional public health method of collecting information from a sample to understand health in the population from which the sample came. Holding public

health activities to a standard of studying every case in order to classify an activity as non-research is not practical or reasonable.

General Attributes of Non-Research - Intent of the project is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants'community; data collected are needed to assess and/or improve the program or service, the health of the participants or the participants'community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental.

Other attributes, such as publication of findings, statutory authority (see discussion in next section), methodological design, selection of subjects, and hypothesis testing/generating, do not necessarily differentiate research from non-research because these types of attributes can be shared by both research and non-research projects.

A non-research project may generate generalizable knowledge after the project is undertaken even though generating this knowledge was not part of the original, primary intent. In this case, since the primary intent was not to generate or contribute to generalizable knowledge, the project is not classified as research at the outset. However, if subsequent analysis of identifiable private information is undertaken to generate or contribute to generalizable knowledge, the analysis constitutes human subjects research that requires IRB review.

If a project includes multiple components and at least one of those components is designed to generate generalizable knowledge, then the entire project is classified as research unless the components are separable.

II. Specific

A. Surveillance - Surveillance is a term describing a method for public health data collection. Surveillance systems may be either research or non-research. Surveillance systems are likely to be non-research when they involve the regular, ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in the population. Data generated by these systems are used to manage public health programs. They have in place the ability to invoke public health mechanisms to prevent or control disease or injury in response to an event. Thus, the primary intent of these surveillance systems is to prevent or control disease or injury in a defined population by producing information about the population from whom the data were collected. These attributes of surveillance that is non-research are generally found in state statute or regulation where the intent of the activity, its purposes, and uses of the data are specified. Surveillance systems that most easily fit into this category are ones in which the data are limited to describing the occurrence of a health-related problem

(disease reporting) and systems in which no analytic (etiologic) analyses can be conducted. Subjects are rarely selected according to a design; rather, all cases are entered into the surveillance system because they are passive reporting systems. Hypothesis testing is not part of the system.

Surveillance systems are likely to be research when they involve the collection and analysis of health-related data conducted either to generate knowledge that is applicable to other populations and settings than the ones from which the data were collected or to contribute to new knowledge about the health condition. The information gained from the data collection system may or may not be used to invoke public health mechanisms to prevent or control disease or injury, but this is not a primary intent of the project. Thus, the primary intent of these surveillance systems is to generate generalizable knowledge. Characteristics of surveillance systems that most easily fit into this category are: longitudinal data collection systems (e.g., follow-up surveys and registries) that allow for hypothesis testing; the scope of the data is broad and includes more information than occurrence of a health-related problem; analytic analyses can be conducted; and cases may be identified to be included in subsequent studies.

In general, lawful state disease reporting, monitoring requirements and other data collection activities conducted under state statute or under recognized public health authority are non-research. Disease reporting activities are not research. Disease reporting, for these purposes, is defined narrowly to include the reporting of the specific health condition or disease, demographic information; and accepted, known risk factors as specified in state statutes or regulations. When reporting systems collect data beyond standard reporting information, the reporting activity is not automatically considered to be non-research. Collection of data that would allow etiologic analysis is likely to be research.

If other activities are added to a surveillance project with the specific intent of generating new or generalizable knowledge, these additional activities are considered to be research. It becomes important to distinguish between disease reporting activities that are non-research and uses of the reported data that may be either non-research or research.

Sometimes, CDC funds state and local health departments to establish surveillance systems with dual intentions on the part of CDC: to build state capacity in disease reporting and for CDC to generate new knowledge. Disease reporting activities conducted at the state level are generally non-research. However, if CDC uses the data collected through such reporting to generate new knowledge, CDC would be engaged in research. CDC may consider state health departments to be engaged in the research depending upon their role. If state health departments are participating beyond merely providing the data, they may be considered as engaged in the research. Institutions

providing information to state health departments would not be considered engaged in the research (see OPRR memorandum dated 1/26/99).

Some surveillance projects do not fit easily into the categories described above. For these projects, the primary intent and elements of the project must be examined carefully.

B. Emergency Responses - Most emergency responses tend to be non-research because these projects are undertaken to identify, characterize, and solve an immediate health problem and the knowledge gained will directly benefit those participants involved in the investigation or their communities. However, an emergency response may have a research component if: 1) samples are stored for future use intended to generate generalizable knowledge or 2) additional analyses are conducted beyond those needed to solve the immediate health problem. When investigational new drugs are used or drugs are used off-label, the emergency response is almost always research. The same applied to medical devices. For emergency responses, whenever a systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs, the activity is research.

C. Evaluation – The terms "evaluation" and "program evaluation" are used interchangeably. Yet, there are subtle differences between the two terms (see definitions and reference provided above). Evaluation is a term, broad in meaning, that refers to the systematic use of scientific methods to measure efficacy, implementation, utility, and so on of a program in its entirety or its components. Evaluations may or may not be research. Program evaluations are a subset of evaluations. As defined here program evaluations are almost never research.

When the purpose of an evaluation is to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective, the evaluation is research. The systematic comparison of standard or non-standard interventions in an experimental-type design is research. In these cases, the knowledge gained is applicable beyond the individual, specific program. Thus, the primary intent is to generate new knowledge or contribute to the knowledge in the scientific literature. Further, it is intended to apply the knowledge to other sites or populations.

When the purpose is to assess the success of an established program in achieving its objectives in a specific population and the information gained from the evaluation will be used to provide feedback to that program, the evaluation, referred to as program evaluation, is non-research. In the non-research scenario, the evaluation is used as a management tool to monitor and improve the program. The evaluation activity is often a component of the regular, ongoing program. Information learned from the evaluation has

immediate benefit for the program and/or the clients receiving the services or interventions. The information is often not generalizable beyond the individual program. Interventions and services that are evaluated are never experimental or new; they are known (either from empirical data or through consensus) to be effective.

Sometimes, the term "formative evaluation" is used to describe data collection activities that occur prior to the implementation of an intervention, service, or program. Whether the "formative evaluation" is research or non-research depends upon its intent. If the evaluation is conducted prior to implementing a new, modified, or previously untested intervention, the evaluation is part of the overall research project. If the evaluation is conducted to provide information on how to tailor a proven-effective intervention, service, or program in a specific setting or context, the evaluation is not research.

Evaluations of CDC's national programs, i.e., programs that CDC funds to all state health departments and in which evaluation is one component, are not research. These evaluation activities are on-going and involve generally the collection of minimal, standard data elements across all sites. The data are generally used at the local level as a management tool as well as at the national level for the same purpose. Sometimes, data from these evaluation activities will be aggregated at CDC and used for other purposes. When this occurs, subsequent use of the data may be research.

In some cases, program activities and evaluation activities are separable. For example, interventions or services are being provided; they have a history of being provided and there is an intention to continue to provide them. An evaluation is conducted to determine the efficacy of these program activities. In another example, a public health department, under its public health authority, may provide an untested intervention in an outbreak situation. An evaluation component is added. In both of these examples, because the intervention and evaluation activities are undertaken with different intentions and are separable, the intervention activities are not research but the evaluation activities are research.

APPENDIX

Examples of CDC surveillance, emergency responses, and evaluation activities that are non-research and research.

SURVEILLANCE:

Non-research -

National Notifiable Diseases Surveillance System (NNDSS) - States and territories have asked CDC to act as a common data collection point for data on nationally notifiable diseases. A notifiable disease is considered by the Council of State and Territorial Epidemiologists to be a condition for which regular, frequent, and timely information about individual cases is necessary at the national level for the prevention and control of disease. NNDSS data are collected and published weekly in the Morbidity and Mortality Weekly Report and annually in the Summary of Notifiable Diseases, United States. The NNDSS is essential to the day to day practice of public health. The primary intent of the surveillance system is to provide CDC and state and local health officials with information to detect and control outbreaks of disease. The NNDSS is also used to measure the impact of programs such as immunization. The intended benefits resulting from the NNDSS are for the residents of the states and local areas who contribute data to the system.

Diabetes Surveillance Report - Using public use data from several national surveys, a national diabetes surveillance system is produced. Data from the surveillance system are used to describe the burden of diabetes and its complications on a national and state level. The primary intent of the surveillance system is to provide information for the development of national and state public health priorities and policies regarding the prevention and control of diabetes. The intended benefits are for those who have diabetes or those who are at risk of developing diabetes.

Research -

A Sentinel Surveillance System for Lassa Fever in the Republic of Guinea - Four study sites were selected to identify and describe cases of Lassa fever. Cases were identified from hospital and outpatient admissions. The purpose of the project was to generate baseline information on the Lassa virus and human clinical Lassa fever in the Republic of Guinea. No public health interventions were planned as part of this project; there was no direct benefits for study participants. Thus, the primary intent was to contribute to the knowledge of Lassa fever.

Developmental Disabilities in Very Low Birthweight Children: Linkage of the Georgia Very Low Birthweight Study and the Metropolitan Atlanta Developmental Disabilities

Surveillance Program - The Metropolitan Atlanta Developmental Disabilities Surveillance Program, an ongoing CDC surveillance program to monitor trends in the occurrence of selected developmental disabilities in children living in the metropolitan Atlanta area, and the Georgia Very Low Birthweight Study, conducted in the 1980s to investigate the environmental and other risk factors for very low birthweight were linked for specific investigations of adverse developmental outcomes. Linkage of these primary files provides a unique opportunity to assist efforts to assess the occurrence of selected developmental disabilities in metropolitan Atlanta children and to identify causes of these conditions without the additional time and resource expenditure of additional field data collection. For these investigations involving secondary analyses of the linked primary data sets, no individuals were contacted; only information available from the linkage were used. The purpose of the project was to estimate the prevalence of cerebral palsy, mental retardation, and hearing and visual impairments and to identify pre- and perinatal medical and sociodemographic risk factors for these disabilities in a population-based cohort of very low birthweight children in Atlanta. The primary intent was to generate generalizable knowledge about developmental disabilities.

EMERGENCY RESPONSES:

Non-research -

Outbreak of Gastroenteritis - Three days after a cruise ship left Los Angeles, California for several ports in Mexico, CDC was notified that 24 of 1,899 passengers and 6 of 670 crew had presented to the ship's infirmary with gastrointestinal illness. The purpose of the investigation was to determine the cause and extent of the outbreak and to prevent and control gastrointestinal illness among the ships passengers and crew. Although this type of investigation is often undertaken after the outbreak has occurred and therefore information gained is likely to benefit the ship's next set of cruise passengers and crew, the primary intent of the investigation is to assist in controlling the current disease outbreak.

Recall of Six Lots of Influenza Vaccine - One of the pharmaceutical companies who manufactures influenza vaccine instituted a voluntary recall of six lots of influenza vaccine. The lots were recalled due to decreased potency of the A/Nanchang/933/95 (H3N2) component of the vaccine. CDC was notified by a state health department that a nursing home had vaccinated its residents with the recalled vaccine. The purpose of the investigation was to determine whether residents of this nursing home who received the vaccine had a suboptimal immune response and required revaccination. The primary intent of this investigation was to prevent the occurrence of influenza among the participants if they demonstrated a suboptimal immune response; there was a potential for participants to receive a direct benefit in the form of revaccination if they participated.

Research -

Childhood Exposure to Nicotine-Containing Products in Rhode Island - Between January 1, 1995 and June 30, 1996, 90 cases of nicotine-containing products were reported to the Rhode Island Poison Control Center. No known population-based investigation has been conducted to determine risk factors associated with nicotine-containing products poisoning. The purpose of the Epi-Aid was to determine risk factors associated with childhood exposure to nicotine-containing products, and to develop appropriate control measures. Although there may be some benefit to the 90 children exposed in Rhode Island, the benefits from this study extend beyond the study participants to the population of children who are at risk of exposure to nicotine-containing products. In addition, there was no immediate health problem to be controlled. Thus, the primary intent of the investigation was to generate generalizable knowledge about the risk factors associated with childhood exposure to nicotine-containing products.

Azithromycin Used as Prophylaxis Against the Spread of Illness Due to Mycoplasma Pneumoniae in the Setting of an Outbreak - During the first week of freshman entering a post high school academic institution, a cluster of respiratory illness was recognized by the infirmary staff. Early serologic testing suggest Mycoplasma pneumoniae as the etiologic agent. About four weeks later 42% of the freshman and 17% of the upperclassmen reported a respiratory illness; 50% of those tested had serologic evidence of Mycoplasma pneumoniae infection. The lower attack rate among upperclassmen was likely a consequence of them returning to campus 15 days after the freshmen arrived. A trial of chemoprophylaxis with azithromycin was proposed. Highly effective control measures in the setting of an outbreak have not been described. There is limited information about the role of antimicrobials in controlling an epidemic of Mycoplasma pneumoniae. Thus, the primary intent of the investigation was to generate generalizable knowledge about the efficacy of azithromycin to prevent the spread of Mycoplasma pneumoniae in an outbreak situation.

PROGRAM EVALUATION:

Non-research -

Evaluation of School-based HIV Prevention Program - As part of the evaluation of the school-based HIV prevention program in Denver public schools, principals, teachers, student contact staff, students, and parents were interviewed. HIV program efforts in policy awareness, staff development, curriculum implementation, and status of students receiving HIV prevention education were assessed.

The purpose (primary intent) of the program evaluation was to provide information to Denver public schools that will be used to improve their school-based HIV prevention programs. The

results from the evaluation were used to assess the success of the interventions in a specific population (Denver public school children) and to refine the interventions in that population.

IMPACT Progress Reports - The Office on Smoking and Health awarded 32 states and the District of Columbia health departments cooperative agreements to build capacity to conduct tobacco use prevention and control programs. These cooperative agreements are part of CDC's Initiatives to Mobilize for the Prevention and Control of Tobacco Use (IMPACT), which is a nationwide effort to establish comprehensive, coordinated tobacco use prevention programs. Evaluation of IMPACT is comprised of awardees submitting semi-annual progress reports. Information in the evaluation includes staffing, coalition composition and efforts, status of a state tobacco control plan, development of a resource center, training efforts, community outreach and mobilization, and participation in CDC national campaigns.

The primary intent of these state tobacco control program evaluations is to assess the success of the intervention activities within each state. The information gained from the evaluation is used to refine the interventions in that state. In addition, the information is used nationally to evaluate the success of the IMPACT program.

Research -

Evaluation of Community Based Organization Intervention to Reduce Sexually Transmitted Disease (STD) Rates Among STD Patients in Miami - Male STD Patients were randomized to either the standard HIV prevention counseling or intensive counseling comprised of four sessions of HIV counseling from a community based organization. STD clinic records were reviewed to determine whether there was a difference in return rates with new STDs between the groups. The objective of intervention and evaluation is to determine whether intensive counseling reduces the acquisition of new STDs among high risk people attending a STD clinic. The purpose of the project was to evaluate a new intervention for reducing the transmission of STDs. Knowledge gained from this evaluation would be used to generalize to other sites.

A Comprehensive Evaluation for Project DIRECT (Diabetes Intervention: Reaching and Educating Communities Together) - Project DIRECT is a community diabetes demonstration project targeting African American adults residing in Raleigh, North Carolina. The project is three-tiered and addresses diabetes care, community screening for persons at high risk for developing diabetes, and population based approaches to increase physical activity and reduce dietary fat intake (two risk factors for diabetes). The goals of the community project are to reduce preventable complications of diabetes via a health systems approach, increase the proportion of persons at risk for diabetes who are screened, and increase the proportion who participate in regular vigorous physical activity and eat a reduced fat diet. Baseline and follow-up population-based surveys are planned to evaluate the community intervention. The purpose of

this project is to evaluate new and innovative interventions to prevent diabetes and its complications. Knowledge gained from this project will be used to develop similar intervention projects in other communities.

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Healthy People 2010Õ Conference Edition

3
Cancer

Co-Lead Agencies: Centers for Disease Control and Prevention;
National Institutes of Health

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Goal

Reduce the number of new cancer cases as well as the illness, disability, and death caused by cancer.

Overview

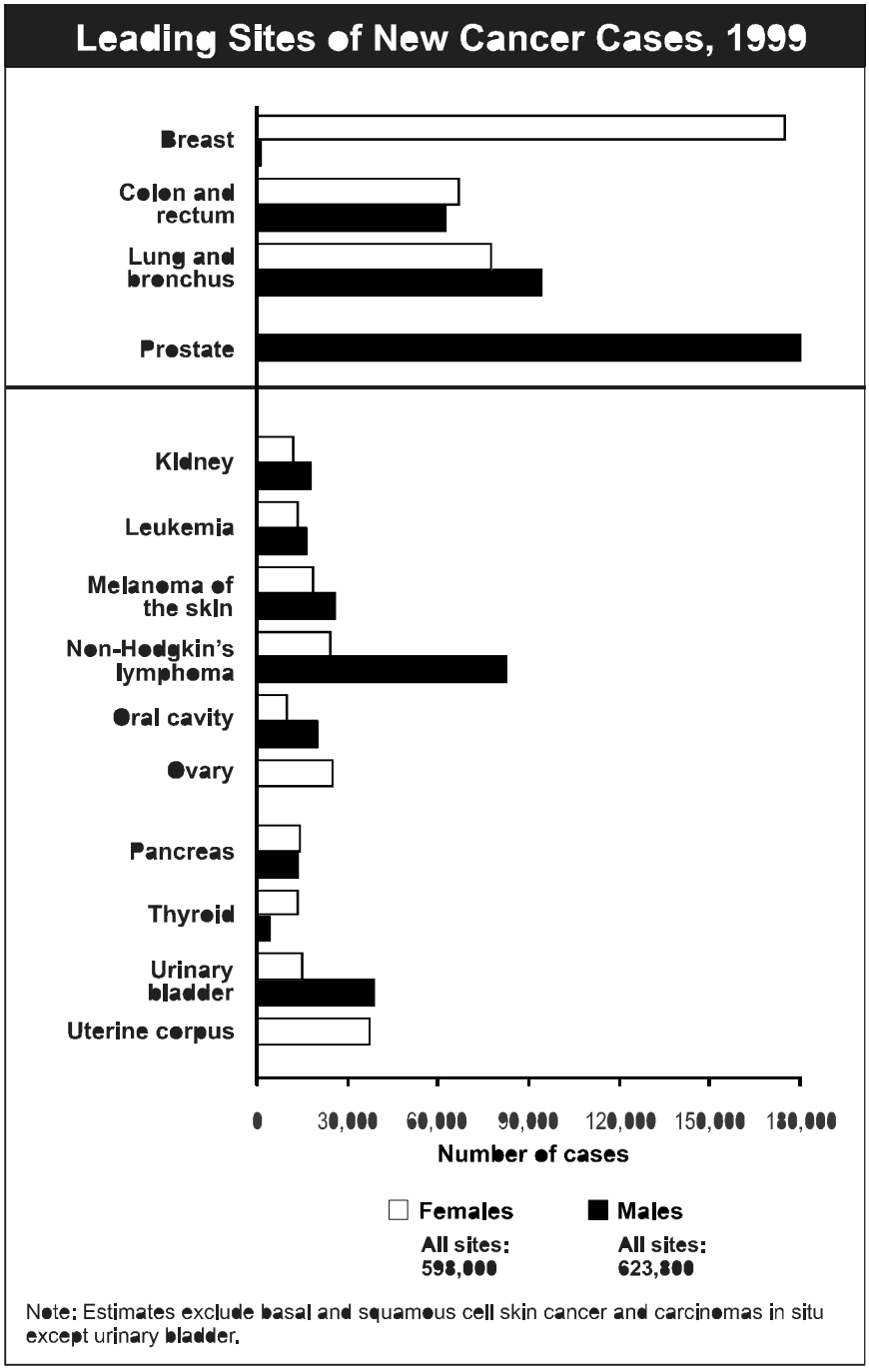
Cancer is the second leading cause of death in the United States. During 1999, an estimated 1,221,800 persons in the United States were diagnosed with cancer; 563,100 persons were expected to die from cancer.[1] These estimates did not include most skin cancers, and new cases of skin cancer are estimated to exceed 1 million per year. One-half of new cases of cancer occur in people aged 65 years and over[2].

About 491,400 Americans who get cancer in a given year, or 4 in 10 patients, are expected to be alive 5 years after diagnosis. When adjusted for normal life expectancy (accounting for factors such as dying of heart disease, injuries, and diseases of old age), a "relative" 5-year survival rate of 60 percent is seen for all cancers.[1] This rate means that the chance of a person recently diagnosed with cancer being alive in 5 years is 60 percent of the chance of someone not diagnosed with cancer. Five-year relative survival rates commonly are used to monitor progress in the early detection and treatment of cancer and include persons who are living 5 years after diagnosis, whether in remission, disease free, or under treatment.

Issues and Trends

Cancer death rates for all sites combined decreased an average of 0.6 percent per year from 1990 to 1996.[3] This decrease occurred after rates had increased by 0.4 percent per year from 1973 to 1990.[4] Death rates for male lung, female breast, prostate, and colorectal cancers decreased significantly during the 1990-96 period[3]. The lung and bronchus, prostate, female breast, and colon and rectum were the most common cancer sites for all racial and ethnic populations in the United States and together accounted for approximately 54 percent of all newly diagnosed cancers[1].

In addition to the human toll of cancer, the financial costs of cancer are substantial[5]. The overall annual costs for cancer are estimated at $107 billion, with $37 billion for direct medical costs (the total of all health expenditures), $11 billion for costs of illness (the cost of low productivity due to illness), and $59 billion for costs of death (the cost of lost productivity due to death). Treatment for lung, breast, and prostate cancers alone accounts for more than half of the direct medical costs.



Source: American Cancer Society, *Surveillance Research,* 1999.

Disparities

Cancer death rates vary by gender, race, and ethnicity.[3] Male cancer death rates peaked in 1990 at 220.8 per 100,000, and female death rates peaked a year later at 142.2 per 100,000. After the peak year, through 1996, male cancer deaths for all sites decreased on average by 1 percent per year, and female deaths decreased on average by 0.4 percent per year. There were significant decreases in mortality for lung, prostate, brain, and other nervous system cancers in males and a significant

decrease in breast cancer mortality for females[3]. Among males, lung cancer death rates have declined since 1990. In contrast, lung cancer death rates have continued to increase among females. Since 1987, more females have died from lung cancer than breast cancer.

African Americans are about 34 percent more likely to die of cancer than are whites and more than two times more likely to die of cancer than are Asian/Pacific Islanders, American Indians, and Hispanics[3]. African American women are more likely to die of breast and colon cancers than are women of any other racial and ethnic group, and they have approximately the same lung cancer mortality rates as white women. African American men have the highest mortality rates of colon and rectum, lung, and prostate cancers. Age-adjusted lung cancer death rates are approximately 40 percent higher among African American males than white males. Little difference in age-adjusted lung cancer death rates has been observed between African American females and white females. Hispanics have higher rates of cervical, esophageal, gallbladder, and stomach cancers. Similarly, some specific forms of cancer affect other ethnic groups at rates higher than the national average (for example, stomach and liver cancers among Asian American populations and colon and rectum cancer among Alaska Natives). Racial and ethnic groups have lower survival rates than whites for most cancers[1].

Differences between the races represent both a challenge to understand the reasons and an opportunity to reduce illness and death and to improve survival rates.

The Hispanic cancer experience also differs from that of the non-Hispanic white population, with Hispanics having higher rates of cervical, esophageal, gallbladder, and stomach cancers. New cases of female breast and lung cancers are increasing among Hispanics, who are diagnosed at later stages and have lower survival rates than whites.

The recent decrease in deaths from breast cancer in white females is attributed to greater use of breast cancer screening in regular medical care. However, new cases of breast cancer in African American females continue to increase, and deaths continue to increase as well, in part, because breast cancer is diagnosed at later stages in African American females[4].

Data on colorectal cancer (CRC) show a decline in new cases and death rates in white males and females, stable new case rates in African Americans, and a continued rise in death rates in African American males. Five-year survival rates are 64 percent in whites and 52 percent in African Americans (1989-94). Early detection and treatment play a key role in these survival rates.

New cases of prostate cancer peaked in 1992 at 190.8 per 100,000 people and declined on average by 8.5 percent each year from 1992 to 1996. Prostate cancer death rates peaked in 1991 at 26.7 per 100,000 people; rates decreased on average

by 2.1 percent each year from 1991 to 1995. Causes of the trends are unclear but may be attributed to a number of factors that are under investigation.

Possible disparities regarding the health status of lesbian women and possible barriers to access to health services by lesbians have been identified by the Institute of Medicine as a research priority.[6]

Opportunities

Evidence suggests that several types of cancer can be prevented and that the prospects for surviving cancer continue to improve. The ability to reduce cancer death rates depends, in part, on the existence and application of various types of resources. First, the means to provide culturally and linguistically appropriate information on prevention, early detection, and treatment to the public and to health care professionals are essential. Second, mechanisms or systems must exist for providing people with access to state-of-the-art preventive services and treatment. Where suitable, participation in clinical trials also should be encouraged. Third, a mechanism for maintaining continued research progress and for fostering new research is essential. Genetic information that can be used to improve disease prevention strategies is emerging for many cancers and may provide the foundation for improved effectiveness in clinical and preventive medicine services.

To provide new opportunities for cancer prevention and control in the future, there is a continuing and vital need to foster new, innovative research on both the causes of cancer (including genetic and environmental causes) and on methods to translate biologic and epidemiologic findings into effective prevention and control programs for use by government and community organization to further reduce the Nation's cancer burden.

These needs can be met, in part, with the network of cancer control resources now in place. This network has the organizational and personnel capabilities for various cancer interventions. Despite the extent of these resources, they alone are insufficient to reduce deaths from cancer. Gaps exist in information transfer, optimal practice patterns, research capabilities, and other areas. These must be recognized and filled to meet cancer prevention and control needs.

It is estimated that as much as 50 percent or more of cancer can be prevented through smoking cessation and improved dietary habits, such as reducing fat consumption and increasing fruit and vegetable consumption.[7, 8] Physical activity and weight control also can contribute to cancer prevention.[9, 10]

Scientific data from randomized trials of cancer prevention together with expert opinions suggest that compliance with screening recommendations for cancer of the breast, cervix, and colon/rectum could reduce deaths from these cancers.

To reduce breast cancer deaths, a high percentage of females in the United States aged 40 years and older need to comply with screening recommendations. A reduction in breast cancer deaths could be expected to occur after a delay of roughly 7 years.[11] To reduce cervical cancer deaths, a high percentage of females in the United States who are aged 18 years and older need to comply with screening recommendations. Evidence from randomized preventive trials is unavailable, but expert opinion suggests that a beneficial impact on cervical cancer death rates would be expected to occur after a delay of a few years.

Evidence shows that a reduction in CRC deaths can be achieved through detection and removal of precancerous polyps and treatment of CRC in its earliest stages. The findings from three randomized controlled trials indicate that biennial screening with fecal occult blood tests (FOBT) can reduce deaths from CRC by 15 to 21 percent in people aged 45 to 80 years.[12, 13, 14] One trial[15] reported a 33 percent reduction in deaths with annual screening in the same age groups, and a simulation model showed a 56 percent reduction.[16] The efficacy of sigmoidoscopy has been supported by three case-control studies[17, 18, 19] that showed 59 to 79 percent reductions in CRC deaths from cancers within reach of the sigmoidoscope in age groups 45 years and older.

Prostate cancer interventions that include preventive strategies are not available at this time because it is unclear whether any of the factors that increase the risk of prostate cancer can be changed. Race and age are risk factors: African Americans and older men are at higher risk. Widespread prostate cancer screening should be approached with caution until the results of clinical trials provide evidence that screening does more good than harm.[20] Some advocates favor screening programs targeting high-risk groups, including African Americans and males with a positive family history of prostate cancer. However, there is no clinical evidence that screening tests should be performed with these high-risk groups.

Melanoma and other skin cancers were expected to claim the lives of almost 9,200 persons in 1999.[1] Insufficient evidence exists to determine whether routine skin examinations (self or physician) decrease deaths from melanoma or other skin cancers. However, many of the skin cancers diagnosed each year could be prevented by limiting exposure to the sun, by wearing protective clothing, and by using sunscreen. Research into the genetic risk of disease may provide the basis for identifying the individuals most at risk and the preventive methods best tailored for reducing those risks.

For all cancers, treatments designed to increase survival are needed along with improved access to state-of-the-art care. In addition to measurements of survival,

indices of quality of life for both the short term and long term are regarded as important considerations.

Interim Progress Toward Year 2000 Objectives

The Healthy People 2000 objective for total cancer deaths was achieved for the total population by 1995. Lung cancer deaths declined for the first time in 50 years in 1991, declined again in 1992, remained level in 1993, and then dropped again in 1994, 1995, and 1996. The decline in the age-adjusted death rate for CRC for the total population has gone beyond the year 2000 target, but declines in death rates have not been as substantial for the black population. Improvements were observed in cancer risk factors, such as tobacco use and dietary fat intake. Data also showed some improvement in the proportion of women receiving mammograms and Pap tests. In addition, for both mammograms and Pap tests, the disparity in use rates for most of the population subgroups and those for all women either has been reduced or eliminated.

Note: Unless otherwise noted, data are from Centers for Disease Control and Prevention, National Center for Health Statistics, *Healthy People 2000 Review, 1998-99.*

Healthy People 2010—Summary of Objectives

Cancer

Goal: Reduce the number of new cancer cases as well as the illness, disability, and death caused by cancer.

Number	Objective
3-1	Cancer deaths
3-2	Lung cancer deaths
3-3	Breast cancer deaths
3-4	Cervical cancer deaths
3-5	Colorectal cancer deaths
3-6	Oropharyngeal cancer deaths
3-7	Prostate cancer deaths
3-8	Melanoma cancer deaths
3-9	Sun exposure
3-10	Provider counseling about preventive measures
3-11	Pap tests
3-12	Colorectal cancer screening
3-13	Mammograms
3-14	Statewide cancer registries
3-15	Cancer survival

Healthy People 2010 Objectives

3-1. Reduce the overall cancer death rate.

Target: 158.7 cancer deaths per 100,000 population.

Baseline: 201.4 cancer deaths per 100,000 population in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: 21 percent improvement.

Data source: National Vital Statistics System (NVSS), CDC, NCHS.

Total Population, 1997*	**Cancer Deaths** Rate per 100,000
TOTAL	205.7
Race and ethnicity	
American Indian or Alaska Native	131.8
Asian or Pacific Islander	127.2
Asian	DNC
Native Hawaiian and other Pacific Islander	DNC
Black or African American	262.1
White	202.2
Hispanic or Latino	125.5
Not Hispanic or Latino	210.4
Black or African American	268.5
White	205.7
Gender	
Female	171.6
Male	258.0
Education level (aged 25 to 64 years)	
Less than high school	137.1
High school graduate	141.6
At least some college	82.3

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

3-2. Reduce the lung cancer death rate.

Target: 44.8 deaths per 100,000 population.

Baseline: 57.4 lung cancer deaths per 100,000 population in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: 22 percent improvement.

Data source: National Vital Statistics System (NVSS), CDC, NCHS.

Total Population, 1997*	**Lung Cancer Deaths** Rate per 100,000
TOTAL	58.1
Race and ethnicity	
American Indian or Alaska Native	36.3
Asian or Pacific Islander	28.9
Asian	DNC
Native Hawaiian and other Pacific Islander	DNC
Black or African American	67.9
White	58.0
Hispanic or Latino	23.9
Not Hispanic or Latino	60.2
Black or African American	69.6
White	59.9
Gender	
Female	41.4
Male	81.6
Education level (aged 25 to 64 years)	
Less than high school	48.3
High school graduate	42.0
At least some college	18.4

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

Lung cancer is the most common cause of cancer death among both females and males in the United States. Estimates indicated that 171,600 (77,600 females and 94,000 males) new cases of lung cancer would be diagnosed in 1999; 158,900 persons (68,000 females and 90,900 males) would die from lung cancer in 1999, accounting for 28 percent of all cancer deaths.[1]

Cigarette smoking is the most important risk factor for lung cancer, accounting for 68 to 78 percent of lung cancer deaths among females and 88 to 91 percent of lung

cancer deaths among males.[21] Other risk factors include occupational exposures (radon, asbestos) and indoor and outdoor air pollution (radon, environmental tobacco smoke).[22] One to two percent of lung cancer deaths are attributable to air pollution.[23] Smoking cessation decreases the risk of lung cancer to 30-50 percent of that of continuing smokers after 10 years of abstinence.[7]

3-3. Reduce the breast cancer death rate.

Target: 22.2 deaths per 100,000 females.

Baseline: 27.7 breast cancer deaths per 100,000 females in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: 20 percent improvement.

Data source: National Vital Statistics System (NVSS), CDC, NCHS.

Females, 1997*	**Breast Cancer Deaths** Rate per 100,000
TOTAL	28.6
Race and ethnicity	
American Indian or Alaska Native	13.1
Asian or Pacific Islander	12.6
Asian	DNC
Native Hawaiian and other Pacific Islander	DNC
Black or African American	37.7
White	28.0
Hispanic or Latino	17.8
Not Hispanic or Latino	29.2
Black or African American	38.7
White	28.4
Education level (aged 25 to 64 years)	
Less than high school	21.2
High school graduate	29.6
At least some college	22.9

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

Breast cancer is the most common cancer among women in the United States. An estimated 175,000 new cases were expected to be diagnosed in 1999. About 43,700 U.S. women were expected to die from breast cancer in 1999, accounting for about 16.5 percent of cancer deaths among women.[1] Death from breast cancer

can be reduced substantially if the tumor is discovered at an early stage. Mammography is the most effective method for detecting these early malignancies. Clinical trials have demonstrated that mammography screening can reduce breast cancer deaths by 20 to 39 percent in women aged 50 to 74 years and about 17 percent in women aged 40 to 49 years.[24] Breast cancer deaths can be reduced through increased adherence with recommendations for regular mammography screening.

Many breast cancer risk factors, such as age, family history of breast cancer, reproductive history, mammographic densities, previous breast disease, and race and ethnicity, are not subject to intervention.[25, 26] However, being overweight is a well-established breast cancer risk for post-menopausal women that can be addressed.[25] Avoiding weight gain is one method by which older women may reduce their risk of developing breast cancer.

3-4. Reduce the death rate from cancer of the uterine cervix.

Target: 2.0 deaths per 100,000 females.

Baseline: 3.0 cervical cancer deaths per 100,000 females in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: Better than the best.

Data source: National Vital Statistics System (NVSS), CDC, NCHS.

Females, 1997*	**Cervical Cancer Deaths** Rate per 100,000
TOTAL	3.2
Race and ethnicity	
American Indian or Alaska Native	4.0
Asian or Pacific Islander	3.0
Asian	DNC
Native Hawaiian and other Pacific Islander	DNC
Black or African American	6.5
White	2.8
Hispanic or Latino	3.8
Not Hispanic or Latino	3.1
Black or African American	6.7
White	2.7
Education level (aged 25 to 64 years)	
Less than high school	7.7
High school graduate	5.1
At least some college	2.1

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

Cervical cancer is the 10th most common cancer among females in the United States, with an estimated 12,800 new cases in 1999. The number of new cases of cervical cancer is higher among racial and ethnic minority females than among white females. An estimated 4,800 U.S. females were expected to die from cervical cancer in 1999.[1] Cervical cancer accounts for about 1.8 percent of cancer deaths among females. Infections of the cervix with certain types of sexually transmitted human papilloma virus increases risk of cervical cancer and may be responsible for most cervical cancer in the United States.[27]

Considerable evidence suggests that screening can reduce the number of deaths from cervical cancer. Invasive cervical cancer is preceded in a large proportion of cases by precancerous changes in cervical tissue that can be identified with a Pap test. If cervical cancer is detected early, the likelihood of survival is almost 100 percent with appropriate treatment and followup; that is, almost all cervical cancer deaths could be avoided if all females complied with screening and followup recommendations.[28] Risk is substantially decreased among former smokers in comparison to continuing smokers.[7]

3-5. Reduce the colorectal cancer death rate.

Target: 13.9 deaths per 100,000 population.

Baseline: 21.1 colorectal cancer deaths per 100,000 population in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: 34 percent improvement.

Data source: National Vital Statistics System (NVSS), CDC, NCHS.

Total Population, 1997*	**Colorectal Cancer Deaths** Rate per 100,000
TOTAL	21.6
Race and ethnicity	
American Indian or Alaska Native	14.5
Asian or Pacific Islander	13.5
Asian	DNC
Native Hawaiian and other Pacific Islander	DNC
Black or African American	28.8
White	21.1

Hispanic or Latino	12.8
Not Hispanic or Latino	22.1
Black or African American	29.5
White	21.4
Gender	
Female	18.4
Male	26.0
Education level (aged 25 to 64 years)	
Less than high school	10.4
High school graduate	12.0
At least some college	7.7

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

Colorectal cancer is the second leading cause of cancer-related deaths in the United States. An estimated 129,400 cases (67,000 females, 62,400 males) of CRC and 56,600 deaths (28,800 females, 27,800 males) from CRC were expected to occur in 1999. When cancer-related deaths are estimated separately for males and females, however, CRC becomes the third leading cause of cancer death behind lung and breast cancer for females and behind lung and prostate cancer for males.

Risk factors for CRC may include age, personal and family history of polyps or colorectal cancer, inflammatory bowel disease, inherited syndromes, physical inactivity (colon only), obesity, alcohol use, and a diet high in fat and low in fruits and vegetables.[29] Detecting and removing precancerous colorectal polyps and detecting and treating the disease in its earliest stages will reduce deaths from CRC. FOBT and sigmoidoscopy are widely used to screen for CRC, and barium enema and colonoscopy are used as diagnostic tests.

3-6. Reduce the oropharyngeal cancer death rate.

Target: 2.6 deaths per 100,000 population.

Baseline: 2.9 oropharyngeal deaths per 100,000 population in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: 10 percent improvement.

Data source: National Vital Statistics System (NVSS), CDC, NCHS.

Total Population, 1997*	**Oropharyngeal Cancer Deaths** Rate per 100,000
TOTAL	3.0

Total Population, 1997*	**Oropharyngeal Cancer Deaths** Rate per 100,000
Race and ethnicity	
American Indian or Alaska Native	2.6
Asian or Pacific Islander	2.5
Asian	DNC
Native Hawaiian and other Pacific Islander	DNC
Black or African American	4.7
White	2.8
Hispanic or Latino	1.8
Not Hispanic or Latino	3.1
Black or African American	4.8
White	2.9
Gender	
Female	1.8
Male	4.6
Education level (aged 25 to 64 years)	
Less than high school	3.5
High school graduate	3.0
At least some college	1.3

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

Oral and pharyngeal cancers comprise a diversity of malignant tumors that affect the oral cavity and pharynx; the overwhelming majority of these tumors are squamous cell carcinomas. In 1999, 29,000 new cases of oropharyngeal cancer were expected to be diagnosed, and approximately 8,100 deaths were expected to occur from the disease. Oropharyngeal cancer is the 10th most common cancer among U.S. men and the 14th most common among U.S. women.[1] Its 5-year survival rate is only 53 percent. The risk of oral cancer is increased in current smokers. Alcohol consumption is an independent risk factor, and when alcohol is combined with use of tobacco products, 90 percent of all oral cancers are explained.[30]

3-7. Reduce the prostate cancer death rate.

Target: 28.7 deaths per 100,000 males.

Baseline: 31.9 prostate cancer deaths per 100,000 males in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: 10 percent improvement.

Data source: National Vital Statistics System (NVSS), CDC, NCHS.

Males, 1997*	**Prostate Cancer Deaths** Rate per 100,000
TOTAL	33.8
Race and ethnicity	
American Indian or Alaska Native	19.3
Asian or Pacific Islander	14.5
Asian	DNC
Native Hawaiian and other Pacific Islander	DNC
Black or African American	71.1
White	31.1
Hispanic or Latino	20.8
Not Hispanic or Latino	34.4
Black or African American	72.5
White	31.5
Education level (aged 25 to 64 years)	
Less than high school	4.2
High school graduate	4.6
At least some college	3.1

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

Prostate cancer is the most commonly diagnosed form of cancer (other than skin cancer) in males and the second leading cause of cancer death among males in the United States. Prostate cancer was expected to account for an estimated 179,300 cases and 37,000 deaths in 1999, or about 27 percent and 14 percent of the cases and deaths due to all cancers, respectively.[1] Prostate cancer is most common in men aged 65 years and older, who account for approximately 80 percent of all cases of prostate cancer.

Digital rectal examination (DRE) and the prostate-specific antigen (PSA) test are two commonly used methods for detecting prostate cancer. Clinical trials of the benefits of DRE and PSA screening are under way, with results expected in the early 21st century.

Although several treatment alternatives are available for prostate cancer, their impact on reducing death from prostate cancer when compared with no treatment in patients with operable cancer is uncertain.[31, 32, 33] Efforts aimed at reducing deaths through screening and early detection remain controversial because of the uncertain benefits and potential risks of screening, diagnosis, and treatment.

3-8. Reduce the rate of melanoma cancer deaths.

Target: 2.5 deaths per 100,000 population.

Baseline: 2.8 melanoma cancer deaths per 100,000 population in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: 11 percent improvement.

Data source: National Vital Statistics System (NVSS), CDC, NCHS.

Total Population, 1997*	**Melanoma Cancer Deaths** Rate per 100,000
TOTAL	2.8
Race and ethnicity	
American Indian or Alaska Native	DSU
Asian or Pacific Islander	0.6
Asian	DNC
Native Hawaiian and other Pacific Islander	DNC
Black or African American	0.6
White	3.1
Hispanic or Latino	0.8
Not Hispanic or Latino	2.8
Black or African American	0.6
White	3.3
Gender	
Female	1.9
Male	4.0
Education level (aged 25 to 64 years)	
Less than high school	1.8
High school graduate	2.8
At least some college	2.3

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

Melanoma, the deadliest of all skin cancers, accounted for an estimated 44,200 new cancer cases and 7,300 deaths in 1999.[1] Trends show annual rises in the number of new cases of 4.3 percent (1973-90) and 2.5 percent (1990-95) and an annual rise in deaths of 1.7 percent (1973-90) followed by a decline of 0.4 percent in 1990-95. In whites, the population at highest risk, death rates are twice as high in males as in females[3].

Although the cause of melanoma is unknown, risk factors include a personal or family history of melanoma, the presence of atypical moles, a large number of moles, intermittent sun exposure, a history of sunburns early in life, freckles, and sun-sensitive skin (as measured by poor tanning ability and light skin, eye, or hair color).[34] Evidence is insufficient to determine whether early detection through routine skin examination (self or physician) decreases the number of deaths from melanoma, but reduced ultraviolet exposure is likely to have a beneficial impact on the risk of melanoma and other skin cancers (basal and squamous cell skin cancers).[33]

3-9. Increase the proportion of persons who use at least one of the following protective measures that may reduce the risk of skin cancer: avoid the sun between 10 a.m. and 4 p.m., wear sun-protective clothing when exposed to sunlight, use sunscreen with a sun protective factor (SPF) of 15 or higher, and avoid artificial sources of ultraviolet light.

3-9a. (Developmental) Increase the proportion of adolescents in grades 9 through 12 who follow protective measures that may reduce the risk of skin cancer.

Potential data source: Youth Risk Behavioral Surveillance System (YRBSS), CDC, NCCDPHP.

3-9b. Increase the proportion of adults aged 18 years and older who follow protective measures that may reduce the risk of skin cancer.

Target: 75 percent of adults aged 18 years and older use at least one of the identified protective measures.

Baseline: 49 percent of adults aged 18 years and older regularly used at least one protective measure in 1998 (preliminary data; age adjusted to the year 2000 standard population).

Target setting method: Better than the best.

Data source: National Health Interview Survey (NHIS), CDC, NCHS. Data on artificial ultraviolet light source are developmental.

Persons Aged 18 Years and Older, 1992*	Type of Protective Measure			
	3-9b. Regularly Used At Least One Pro-	Limited Sun Exposure†	Wore Protective Clothing †	Used Sunscreen†

	Percent			
TOTAL	54	32	29	29
Race and ethnicity				
American Indian or Alaska Native	42	DSU	DSU	DSU
Asian or Pacific Islander	52	38	35	16
Asian	DNA	DNA	DNA	DNA
Native Hawaiian and other Pacific Islander	DNA	DNA	DNA	DNA
Black or African American	54	45	30	9
White	54	30	29	32
Hispanic or Latino	47	35	26	20
Not Hispanic or Latino	54	32	29	29
Black or African American	54	46	31	9
White	54	30	29	33
Gender				
Female	61	39	29	37
Male	46	24	28	20
Education level (aged 25 years and older)				
Less than high school	52	38	30	17
High school graduate	54	34	30	29
Some college	60	32	35	37
Family income level				
Poor	52	39	27	17
Near poor	54	36	30	22
Middle/high income	56	30	29	34
Geographic location				
Urban	54	33	28	30
Rural	52	29	31	26
Disability status				
With activity limitations	57	38	33	27
Without activity limitations	53	31	28	29

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

†Data for limit sun exposure, use sunscreen, and wear protective clothing are displayed to further characterize the issue.

3-10. Increase the proportion of physicians and dentists who counsel their at-risk patients about tobacco use cessation, physical activity, and cancer screening.

Target and baseline:

Objective	Increase Counseling About Tobacco Use Cessation, Physical Activity, and Cancer Screening	1988 Baseline (unless noted)	2010 Target
		Percent	
3-10a.	Internists who counsel about smoking cessation	50	85
3-10b.	Family physicians who counsel about smoking cessation	43	85
3-10c.	Dentists who counsel about smoking cessation	59 (1997)	85
3-10d.	Primary care providers who counsel about blood stool tests	56	85
3-10e.	Primary care providers who counsel about protoscopic examinations	23	85
3-10f.	Primary care providers who counsel about mammograms	37	85
3-10g.	Primary care providers who counsel about Pap tests	55	85
3-10h.	Primary care providers who counsel about physical activity	22 (1995)	85

Target setting method: Better than the best.

Data sources: Survey of Physicians' Attitudes and Practices in Early Cancer Detection, NIH, NCI; National Ambulatory Medical Care Survey (NAMCS), CDC, NCHS; Survey of Current Issues in Dentistry, American Dental Association.

Smoking cessation,[7, 21] adoption of healthy diets,[8] increased physical activity,[9, 10] and increased cancer screening[11, 12, 13, 14, 15, 16, 17, 18, 19] can all contribute to reduced numbers of cancer deaths. Experts recommend that providers screen patients for breast, cervical, and colorectal cancers and counsel patients to prevent or reduce tobacco use, promote physical activity, and promote a healthy diet.[33] Provider counseling should be conducted in a linguistically and culturally appropriate manner.

3-11. Increase the proportion of women who receive a Pap test.

Target and baseline:

Objective	Pap Test	1998 Baseline*	2010 Target
		Percent	
3-11a.	Women aged 18 years and older who have ever received a Pap test.	92	97
3-11b.	Women aged 18 years and older who received a Pap test within the preceding 3 years.	79	90

*Preliminary data; age adjusted to the year 2000 standard population. Includes women without a uterine cervix.

Target setting method: Better than the best.

Data source: National Health Interview Survey (NHIS), CDC, NCHS.

Women Aged 18 Years and Older, 1994*	3-11a. Pap Test Ever	3-11b. Pap Test in Past 3 Years
	Percent	
TOTAL	94	77
Race and ethnicity		
American Indian or Alaska Native	93	68
Asian or Pacific Islander	82	63
Asian	DNA	DNA
Native Hawaiian and other Pacific Islander	DNA	DNA
Black or African American	96	81
White	95	77

Hispanic or Latino	91	71
Not Hispanic or Latino	95	77
Black or African American	96	82
White	95	77
Education level (aged 25 years and older)		
Less than high school	94	66
High school graduate	97	76
At least some college	97	83
Disability status		
With activity limitations	95	74
Without activity limitations	94	78
Family income level		
Poor	91	69
Near poor	94	72
Middle/high income	96	82
Geographic location		
Urban	94	77
Rural	95	76

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population. Includes women without a uterine cervix.

*New data for population groups will be added when available.

3-12. Increase the proportion of adults who receive a colorectal cancer screening examination.

Target and baseline:

Objective	Colorectal Cancer Screening	1998 Baseline*	2010 Target
		Percent	
3-12a.	Adults aged 50 years and older who have received a fecal occult blood test (FOBT) within the preceding 2 years.	34	50
3-12b.	Adults aged 50 years and older who have ever received a sigmoidoscopy	38	50

*Preliminary data; age adjusted to the year 2000 standard population.

Target setting method: Better than the best.

Data source: National Health Interview Survey (NHIS), CDC, NCHS.

Adults Aged 50 Years and Older, 1992*	3-12a. Fecal Occult Blood Test	3-12b. Sigmoidoscopy
	Percent	
TOTAL	30	33
Race and ethnicity		
American Indian or Alaska Native	DSU	DSU
Asian or Pacific Islander	DSU	DSU
Asian	DSU	DSU
Native Hawaiian and other Pacific Islander	DSU	DSU
Black or African American	25	27
White	30	34
Hispanic or Latino	22	28
Not Hispanic or Latino	30	33
Black or African American	25	27
White	31	34
Gender		
Female	30	31
Male	30	36
Education level		
Less than high school	23	28
High school graduate	29	30
At least some college	38	43
Disability status		
Persons with activity limitations	32	37
Persons without activity limitations	28	31
Family income level		
Poor	22	28
Near poor	28	33
Middle/high income	34	36
Geographic location		
Urban	31	34
Rural	25	31

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: crude rates; data are not age adjusted.

*New data for population groups will be added when available.

3-13. Increase the proportion of women aged 40 years and older who have received a mammogram within the preceding 2 years.

Target: 70 percent.

Baseline: 68 percent of women aged 40 years and older received a mammogram within the preceding 2 years in 1998 (preliminary data, age adjusted to the year 2000 standard population).

Target setting method: Better than the best.

Data source: National Health Interview Survey (NHIS), CDC, NCHS.

Women Aged 40 Years and Older, 1994*	**Mammogram** Percent
TOTAL	59
Race and ethnicity	
American Indian or Alaska Native	DSU
Asian or Pacific Islander	49
Asian	DSU
Native Hawaiian and other Pacific Islander	DSU
Black or African American	61
White	59
Hispanic or Latino	51
Not Hispanic or Latino	60
Black or African American	60
White	61
Education level	
Less than high school	47
High school graduate	59
At least some college	67
Family income level	
Poor	43
Near poor	48
Middle/high income	67
Geographic location	
Urban	60
Rural	57
Disability status	
With activity limitations	55
Without activity limitations	61

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Note: Age adjusted to the year 2000 standard population.

*New data for population groups will be added when available.

3-14. Increase the number of States that have a statewide population-based cancer registry that captures case information on at least 95 percent of the expected number of reportable cancers.

Target: 45 States.

Baseline: 21 States in 1999.

Target setting method: 114 percent improvement.

Data sources: National Program of Cancer Registries, CDC; SEER Program, NIH, NCI.

Cancer surveillance serves as the foundation for a national comprehensive strategy to reduce illness and death from cancer. Such surveillance is the indispensable tool that enables public health professionals at the national, State, and community levels to better understand and tackle the cancer burden while advancing clinical, epidemiological, and health services research. In addition, surveillance data from cancer registries, such as cancer incidence and deaths, stage at diagnosis, treatment, and demographics of cancer patients, are essential for planning and evaluating cancer control programs, allocating preventive and treatment resources, targeting and conducting research, and responding to concerns from citizens about the occurrence of cancer in their communities.

Population-based State cancer registries that provide accurate, complete, and timely data are a critical component of the public health infrastructure in the United States. The National Program of Cancer Registries (NPCR) provides funds to 45 States to assist in planning or enhancing cancer registries; develop model legislation and regulations for programs to increase the viability of registry operations; set standards for data quality, completeness, and timeliness; provide training for registry personnel; and help establish computerized reporting and data processing systems. The National Cancer Institute's SEER Program covers the remaining 5 States.

3-15. Increase the proportion of cancer survivors who are living 5 years or longer after diagnosis.

Target: 70 percent.

Baseline: 59 percent of persons with invasive cancer of any type were living 5 years or longer after diagnosis in 1989–95.

Target setting method: 19 percent improvement.

Data source: Surveillance, Epidemiology, and End Results (SEER), NIH, NCI.

Persons With Invasive Cancer of Any Type, 1989-95	5 Years or Longer Survival
	Percent
TOTAL	59
Race and ethnicity	
American Indian or Alaska Native	DNA
Asian or Pacific Islander	DNA
Asian	DNA
Native Hawaiian and other Pacific Islander	DNA
Black or African American	48
White	61
Hispanic or Latino	DNA
Not Hispanic or Latino	DNA
Black or African American	DNA
White	DNA
Gender	
Female	61
Male	58
Education level (aged 25 to 64 years)	
Less than high school	DNA
High school graduate	DNA
At least some college	DNA

DNA = Data have not been analyzed. DNC = Data are not collected. DSU = Data are statistically unreliable.

Related Objectives From Other Focus Areas

19. Nutrition and Overweight

19-5. Fruit intake

19-6. Vegetable intake

19-8. Saturated fat intake

19-9. Total fat intake

21. Oral Health

21-6. Early detection of oral and pharyngeal cancer

21-17. Annual examinations for oral and pharyngeal cancer

27. Tobacco Use

27-1. Adult tobacco use

27-2. Youth tobacco use

27-5. Smoking cessation by adults

27-7. Smoking cessation by adolescents

27-8. Insurance coverage of cessation treatment

Terminology

(A listing of all abbreviations and acronyms used in this publication appears in Appendix K.)

Cancer: A term for diseases in which abnormal cells divide without control. Cancer cells can invade nearby tissue and can spread through the bloodstream and lymphatic system to other parts of the body.

Cancer screening: Checking for changes in tissue, cells, or fluids that may indicate the possibility of cancer when there are no symptoms.

Carcinoma: Cancer that begins in the epithelial tissue that lines or covers an organ.

Clinical trials: Research studies that evaluate the effectiveness of new treatment or disease prevention methods on patients.

Digital rectal exam (DRE): A test in which the health care provider inserts a lubricated, gloved finger into the rectum to feel for abnormal areas.

Fecal occult blood test (FOBT): A test to check for small amounts of hidden blood in stool.

Grade: A system for classifying cancer cells in terms of how abnormal they appear under a microscope. The grading system provides information about the probable growth rate of the tumor and its tendency to spread. The systems used to grade tumors vary with each type of cancer. Grading plays a role in treatment decisions.

Malignant: Cancerous.

Mammogram: An x-ray of the breast.

Melanoma: Cancer of the cells that produce pigment in the skin.

Pap (Papanicolaou) test: Microscopic examination of cells collected from the cervix. The Pap test is used to detect cancer, changes in the cervix that may lead to cancer, and noncancerous conditions, such as infection or inflammation.

PSA (prostate-specific antigen) test: A test that measures the level of an enzyme (PSA) in the blood that increases due to diseases of the prostate gland, including prostate cancer.

Risk factor: Something that increases a person's chance of developing a disease.

Sigmoidoscopy: A procedure in which the physician or health care provider looks inside the rectum and the lower part of the colon (sigmoid colon) through a flexible lighted tube. During the procedure, the physician or health care provider may collect samples of tissues or cells for closer examination.

Squamous cells: Flat cells that look like fish scales. These cells are found in the tissue that forms the surface of the skin, the lining of the hollow organs of the body, and the passages of the respiratory and digestive tracts.

Stage: The size and extent of a cancer, including whether the disease has spread from the original site into surrounding tissue and other parts of the body.

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